Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE REVLIMID & THALOMID PURCHASER ANTITRUST LITIGATION	**Civil Action No. 19-7532 (ES) (MAH)** **Consolidated**
MSP RECOVERY CLAIMS, SERIES LLC *et al.*, **Plaintiffs,** **v.** **CELGENE CORPORATION, *et al.*,** **Defendants.**	**Civil Action No. 21-20451 (ES) (MAH)** **OPINION**

SALAS, DISTRICT JUDGE

Plaintiffs Humana, Inc. ("Humana"); Blue Cross and Blue Shield Association, in its capacity as the carrier for the Service Benefit Plan, a/k/a the "Federal Employee Program," a Federal Employee Health Benefits Act Plan ("Blue Cross"); Health Care Service Corporation and Blue Cross and Blue Shield of Florida, Inc. (together "Health Care"); Cigna Corporation ("Cigna"); and Molina Healthcare, Inc. ("Molina") (collectively the "Insurer Plaintiffs"); MSP Recovery Claims, Series LLC; MSPA Claims 1, LLC; MAO-MSO Recovery II, LLC Series PMPI, a segregated series of MAO-MSO Recovery II, LLC; MSP Recovery Claims Series 44, LLC; MSP Recovery Claims PROV, Series LLC; and MSP Recovery Claims CAID, Series LLC (together the "MSP Plaintiffs") filed suit against Defendants Celgene Corporation ("Celgene") and Bristol-Myers Squibb Company ("BMS") (together the "Celgene Defendants") asserting claims against those entities under federal and/or state antitrust laws as well as state unfair competition laws and

for unjust enrichment.[1] The MSP Plaintiffs also brought suit against the Celgene Defendants under the Racketeer Influenced and Corrupt Organizations Act ("RICO") and the Civil Remedies for Criminal Practices Act, Fla. Stat. 77101, *et seq.* ("Florida RICO"). (MSP SAC ¶¶ 583–626 & 659–96). In addition, the MSP Plaintiffs have filed suit against two entities that provide co-pay assistance, Patient Access Network Foundation ("PAN") and Chronic Disease Fund ("CDF") (together "Charity Defendants") asserting claims against those entities under RICO, Florida RICO, state unfair competition laws, and for unjust enrichment. Before the Court are the Celgene Defendants' motions to dismiss the Operative Complaints of all of the aforementioned plaintiffs. (*In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action No. 19-7532 (D.E. No. 104); *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 151)). Likewise, before the Court are the Charity Defendants' motions to dismiss all claims asserted against them by the MSP Plaintiffs. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 149 & 150)). Having considered the parties' submissions and having held oral argument on the Celgene Defendants' motions on August 18, 2023 and September 8, 2023, the Court is prepared to rule. For the following reasons, the Celgene Defendants' and Charity Defendants' motions are **GRANTED** and the Insurer Plaintiffs' and MSP Plaintiffs' Operative Complaints are dismissed in their entirety.

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[1] The operative complaints in this matter are as follows: (i) *Humana, Inc. v. Celgene Corporation et al.*, Civil Action No. 19-7532 (D.E. No. 68 ("Humana Am. Compl.")); (ii) *Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53); (iii) *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93); (iv) *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686 (D.E. No. 40); (v) *Molina Healthcare, Inc. v. Celgene Corporation, et al.*, Civil Action No. 22-4561 (D.E. No. 7) (together "Insurer Cases"); and (vi) *MSP Recovery Claims Series LLC et al. v. Celgene Corporation et al.*, Civil Action No. 21-20451 ("MSP Case") (D.E. No. 71 ("MSP SAC")) (altogether, "Operative Complaints"). Because the Operative Complaints in the Insurer Cases are nearly identical, the Court will be citing to the Amended Complaint at Docket Entry Number 68 in *Humana Inc. v. Celgene Corp.*, Civil Action Number 19-7532, as the representative complaint in the Insurer Cases. The Court will otherwise cite to the MSP Plaintiffs' Second Amended Complaint at Docket Entry Number 71 in Civil Action Number 21-20451. Unless otherwise noted, the Court's citations to docket entry numbers correspond to the docket entry numbers in Civil Action Number 19-7532.

I. BACKGROUND

A. Factual Overview[2]

The thrust of the allegations made by the Insurer Plaintiffs and MSP Plaintiffs is that Celgene, a brand manufacturer of pharmaceutical products, engaged in a series of conduct over the course of multiple years to exclude generic entry into the market for a brand drug named Revlimid.[3] The MSP Plaintiffs also allege that Celgene engaged in conduct to exclude generic entry into the market for a brand drug named Thalomid. The Insurer Plaintiffs and MSP Plaintiffs allege that, as a result of Celgene's conduct, they have purchased Revlimid at supracompetitive prices. The MSP Plaintiffs also allege that they have purchased Thalomid at supracompetitive prices.

Celgene is a branded drug company that manufactures and distributes two life-saving but dangerous drugs: Thalomid and Revlimid. (Humana Am. Compl. ¶¶ 4–5). The active ingredients in these drugs are thalidomide and lenalidomide, respectively. (*Id.* ¶ 4). In the mid-1900s, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women.

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[2] The Court notes that though many of the MSP Plaintiffs' allegations overlap with the Insurer Plaintiffs' allegations, their allegations are distinct in many respects. (*Compare* MSP SAC *with* Humana Am. Compl.). Nevertheless, at oral argument, the MSP Plaintiffs suggested, without citing any authority for the proposition, that they could stand on the allegations alleged by the Insurer Plaintiffs because they were directed to file an omnibus opposition in response to Celgene's motion to dismiss and thus have been treated as one with the Insurer Plaintiffs. (D.E. No. 252 ("Tr. of Sept. 8, 2023 Oral Arg.") at 19:6–20:4). To the extent that the MSP Plaintiffs argue that they can stand on allegations that were never alleged in their Second Amended Complaint to survive the Celgene Defendants' motion to dismiss, the Court disagrees. In order to review the adequacy of the MSP Plaintiffs' pleadings, the Court will only look to the allegations that are set forth in their Second Amended Complaint. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). And regardless, for the reasons that will be explained in this Opinion, because the Court dismisses the Insurer Plaintiffs' operative complaints in their entirety, any attempt by the MSP Plaintiffs to stand on the sufficiency of their allegations is unavailing.

[3] While the Insurer Plaintiffs raised a number of allegations in their Operative Complaints regarding a separate drug manufactured by Celgene, called Thalomid, the Insurer Plaintiffs clarified, both in their opposition brief and at oral argument, that they are neither pursuing any stand-alone claims based on Celgene's conduct related to Thalomid, nor seeking any Thalomid damages. (D.E. No. 105 ("Opp. Br.") at 2 n.1; D.E. No. 231 ("Tr. of Aug 18, 2023 Oral Arg.") at 31:10–16). In contrast, the MSP Plaintiffs clarified that they are pursuing stand-alone Thalomid claims based on Celgene's conduct in refusing to sell samples of Thalomid to generic manufacturers and in providing co-pay assistance for that drug. (Tr. of Sept. 8, 2023 Oral Arg. at 89:2–11).

(*Id.* ¶ 99). However, because thalidomide caused life-threatening fetal deformities and birth defects, it was banned worldwide. (*Id.* ¶ 100). That ban was in effect until July 16, 1998, when the federal Food & Drug Administration ("FDA") approved Celgene's New Drug Application ("NDA") to reintroduce a version of it into the market as "Thalomid" for an alternative use—to treat erythema nodosum leprosum ("ENL"), a form of leprosy. (*Id.*). To mitigate fetal exposure to the drug, the FDA conditioned its approval of Celgene's NDA for Thalomid in 1998 on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, a program for distributing the drug in accordance with strict safety protocols. (*Id.*). In 2007, Congress gave the FDA statutory authority to condition the approval of drug applications on acceptable safety protocols, called Risk Evaluation and Mitigation Strategies ("REMS"). (*Id.* ¶¶ 61–64). After the FDA codified its REMS distribution program, the FDA approved Celgene's supplemental NDA containing a proposed REMS program for Thalomid on August 3, 2010. (*Id.* ¶ 101).

In 2005, Celgene received approval to manufacture and market Revlimid, a "thalidomide analogue" to treat patients with transfusion dependent anemia. (*Id.* ¶ 103). Revlimid is also an immunomodulatory drug that works against cancer cells. (*Id.*). Like Thalomid, Revlimid is subject to a REMS distribution program (RevAssist) to prevent fetal exposure to the drug. (*Id.* ¶ 104). In its letter to Celgene approving Revlimid, the FDA noted that RevAssist was "an important part of the post-marketing risk management" for the drug. (*Id.*). Celgene holds many patents protecting aspects of Revlimid. (*Id.* ¶ 109).

Despite Celgene's patents, the Insurer Plaintiffs and MSP Plaintiffs claim that Celgene unlawfully monopolized the relevant market for Revlimid in several ways. *First*, the Insurer Plaintiffs and MSP Plaintiffs claim that Celgene unlawfully denied generic drug manufacturers

samples of Revlimid to prevent them from developing generic versions of the drug. (*Id.* ¶¶ 111–234; MSP SAC ¶¶ 116–259). The MSP Plaintiffs also allege that Celgene engaged in similar conduct with respect to Thalomid. (MSP SAC ¶¶ 116–259). *Second*, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene entered into an anticompetitive settlement agreement with a generic manufacturer to delay that generic manufacturer from launching a generic version of Revlimid. (Humana Am. Compl. ¶¶ 364–375 & 418–440; MSP SAC ¶¶ 380–81). *Third*, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene obtained some of the patents covering Revlimid by fraud on the U.S. Patent and Trademark Office ("USPTO"). (Humana Am. Compl. ¶¶ 259–276 & 301–321; MSP SAC ¶¶ 264–66, 270 & 272–342). *Fourth*, the Insurer Plaintiffs and MSP Plaintiffs claim that Celgene filed sham litigations in court to delay and exclude generic entry into the relevant market for Revlimid. (Humana Am. Compl. ¶¶ 337–539; MSP SAC ¶¶ 367–469). *Fifth*, the MSP Plaintiffs, specifically, claim that Celgene made unlawful donations to two co-pay assistance charities, CDF and PAN to fund patient copays of its Thalomid and Revlimid drugs. (MSP SAC ¶¶ 502–52).

To understand the thrust of these claims, the Court will first outline features of the Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as the "Hatch-Waxman Act"—which governs brand and generic competition in the pharmaceutical drug industry. It will then outline the Insurer Plaintiffs' and MSP Plaintiffs' allegations in greater detail.

i. Regulatory Background

a. The Hatch-Waxman Act

With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585, commonly known as the "Hatch-Waxman Act," Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," *see* H.R. Rep. No. 98–857,

pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, *see* H.R. Rep. No. 98–857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this goal, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107–167, at 4 (2001). The resulting regulatory framework has the following five relevant features.

First, a new drug—that is, a pioneer, "brand-name" drug—cannot be introduced until it is approved by the FDA. 21 U.S.C. § 355(a). An applicant for such a drug must submit an NDA, which requires the applicant to submit, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use," *id.* § 355(b)(1)(A)(i), as well as comprehensive information about the drug, *id.* § 355(b)(1). This reporting requirement entails "a long, comprehensive, and costly testing process." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

Second, due to the danger that some new drugs pose, the FDA may approve an NDA conditionally through a REMS program. 21 U.S.C. § 355-1. A REMS program can include a medication guide, a patient package insert, a communication plan to healthcare providers, or packaging and disposal requirements. *Id.* § 355-1(e).

Third, once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through the use of abbreviated procedures. The Hatch–Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") specifying that the generic has the "same active ingredients as, and is biologically equivalent" to, the already-approved brand-name drug. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). In this

way, the generic manufacturer can obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval "for a pioneer drug." *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). In order to test for bioequivalence, the generic manufacturer ordinarily must have access to samples of the brand drug. (Humana Am. Compl. ¶¶ 40–41). To conduct such testing, ANDA applicants typically purchase samples from a drug wholesaler or distributor. (*Id.* ¶ 42). The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, "speed[s] the introduction of low-cost generic drugs to market," *Caraco*, 566 U.S. at 405, thereby furthering drug competition.

Fourth, the Hatch-Waxman Act "sets forth special procedures for identifying, and resolving, related patent disputes." *Actavis*, 570 U.S. at 143. "To facilitate the approval of generic drugs as soon as patents allow, the Hatch–Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents." *Caraco*, 566 U.S. at 405. "The statute mandates that a brand submit in its NDA 'the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug.'" *Id.* (citing 21 U.S.C. § 355(b)(1)). If the FDA approves the new drug, it publishes this information, without verification, in its "Orange Book." *Caraco*, 566 U.S. at 405–06. In turn, any manufacturer filing an ANDA to produce a generic version of that pioneer drug must consult the Orange Book and "assure the FDA that [the] proposed generic drug will not infringe the brand's patents." *Id.* at 406. The generic can provide this assurance in one of several ways. *See* 21 U.S.C. § 355(j)(2)(A)(vii). It can certify that the brand-name manufacturer has not listed any relevant patents. 21 U.S.C. § 355(j)(2)(A)(vii)(I). It can certify that any relevant patents have expired. *Id.* § 355(j)(2)(A)(vii)(II). It can request approval to market beginning when any still-in-force patents expire. *Id.* § 355(j)(2)(A)(vii)(III). Or, as relevant here, the manufacturer

may tender that assurance with a "paragraph IV certification," stating that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." *Id.* § 355(j)(2)(A)(vii)(IV). But "[f]iling a paragraph IV certification means provoking litigation," *Caraco*, 566 U.S. at 407, because the patent statute treats such a filing as a per se act of infringement. *See* 35 U.S.C. § 271(e)(2)(A). "If the brand-name patentee brings an infringement suit within 45 days, the FDA must then delay approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." *Actavis*, 570 U.S. at 143. "If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)). "Accordingly, the paragraph IV process is likely to keep the generic drug off the market for a lengthy period, but may eventually enable the generic company to market its drug for all approved uses." *Caraco*, 566 U.S. at 407–08.

Fifth, "Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route." *Actavis*, 570 U.S. at 143. From when it first begins marketing its drug or when a court enters judgment finding the challenged patent(s) invalid or unenforceable, the first-filing generic enjoys a 180-day period of exclusivity during which no other generic manufacturer can enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). "During that period of exclusivity no other generic can compete with the brand-name drug." *Actavis*, 570 U.S. at 143–44. "If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* at 144 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). "The 180-day exclusivity period, however, can belong

only to the first generic to file. Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it." *Id.* (citing 21 U.S.C. § 355(j)(5)(D)). Importantly, the brand-name manufacturer is not barred from entering the generic market with its own generic version of the drug—a so-called "authorized generic" or "AG"—during the 180-day exclusivity period. *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 276–77 (4th Cir. 2006); *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); *see also Sanofi–Aventis v. Apotex Inc.*, 659 F.3d 1171, 1175 (Fed. Cir. 2011).

b. Structure of the Generic Market

A generic drug may be either an "AB-rated" generic or an "authorized" generic. (Humana Am. Compl. ¶¶ 27–28 & 51; MSP SAC ¶¶ 42–44). AB-rated generics are deemed by the FDA to be bioequivalent to the brand name drug. (Humana Am. Compl. ¶ 25 n.16). AB-rated generics are developed and made by a company other than the company that makes the brand-name drug and, according to the Insurer Plaintiffs' allegations, when a company enters a market with an AB-rated generic, the generic typically captures about 90% of the branded drug's sales within one year—and sells for about 15% of the brand name drug's price. (*Id.* ¶ 28). Under the Hatch-Waxman Act, the first company that applies to produce an AB-rated generic by filing a paragraph IV certification receives the 180-day period of exclusivity described above, during which "no other generic can compete with the brand-name drug." *Actavis*, 570 U.S. at 143–44. An AG, by contrast, is essentially a brand-name drug produced by a brand manufacturer but marketed under a generic label. (Humana Am. Compl. ¶ 51); *Sanofi–Aventis v. Apotex Inc.*, 659 F.3d 1171, 1174 (Fed.Cir.2011). Other than the fact that an AG does not have the brand name on its label, "it is the exact same drug product as the branded product." (Humana Am. Compl. ¶ 51). Unlike AB-rated generics, AGs are marketed and sold either by the brand manufacturer itself or another company

with the brand company's permission. *Sanofi–Aventis*, 659 F.3d at 1174. Regardless of who markets them, AGs and AB-rated generics compete. (Humana Am. Compl. ¶¶ 74–77). AGs in fact enjoy an opportunity for competition that other generics lack. That unique opportunity is an AG's ability to compete with an AB-rated generic that is protected by the Hatch-Waxman Act's 180-day period of exclusivity during which no other AB-rated generic can compete. (*Id.* ¶ 77). AGs are thus the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. *Mylan Pharm., Inc.*, 454 F.3d at 276–77.

ii. The Refusal to Deal Allegations

First, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene monopolized the relevant market for Revlimid by preventing generic drug manufacturers from obtaining samples of Revlimid, which they needed to conduct bioequivalency studies and validation testing necessary for submitting an ANDA (the "refusal to deal allegations"). (*See, e.g.*, Humana Am. Compl. ¶ 111; MSP SAC ¶¶ 116 & 118). The Insurer Plaintiffs and MSP Plaintiffs claim that Celgene used its associated REMS distribution program for Revlimid as a pretext to deny generic manufacturers access to samples of Revlimid, despite exhaustive cautionary measures taken by those competitors to ensure that any bioequivalency study would be conducted in a safe manner. (Humana Am. Compl. ¶ 111; MSP SAC ¶¶ 116 & 118). The MSP Plaintiffs raise similar allegations regarding Thalomid, alleging that Celgene monopolized the relevant market for Thalomid by preventing generic drug manufacturers from obtaining samples of Thalomid which they needed to conduct bioequivalency studies and validation testing necessary for submitting an ANDA. (MSP SAC ¶¶ 116 & 118).[4]

[4] While the Insurer Plaintiffs raised a number of allegations in their Operative Complaints regarding Thalomid, the Insurer Plaintiffs clarified, both in their opposition brief and at oral argument, that they are neither pursuing any stand-alone claims based on Celgene's conduct related to Thalomid, nor seeking any Thalomid damages. (Opp. Br. at 2 n.1; Tr. of Aug 18, 2023 Oral Arg. at 31:10–16). As such, for purposes of the motions before the Court, only

Central to the Insurer Plaintiffs' and the MSP Plaintiffs' refusal to deal allegations is that the FDA approved Thalomid and Revlimid on the condition that both drugs would follow their own REMS programs. (Humana Am. Compl. ¶¶ 100–01 & 104; MSP SAC ¶¶ 113 & 116). Thalomid's program is known as the S.T.E.P.S. (Humana Am. Compl. ¶ 100; MSP SAC ¶ 116). Revlimid's program is called RevAssist. (Humana Am. Compl. ¶ 104; MSP SAC ¶¶ 113 & 116). Due to Celgene's REMS programs on Revlimid and Thalomid, generic manufacturers were unable to purchase samples of the two drugs through normal wholesale distribution channels. (Humana Am. Compl. ¶ 120; MSP SAC ¶ 125). As such, to obtain samples of Revlimid or Thalomid, generic manufacturers were required to purchase samples from Celgene directly. (Humana Am. Compl. ¶ 120; MSP SAC ¶ 125). In other words, Celgene effectively controlled the sale of Thalomid and Revlimid. (Humana Am. Compl. ¶ 120; MSP SAC ¶ 125).

The Insurer Plaintiffs and MSP Plaintiffs allege that Celgene refused to sell samples of Revlimid to several generic drug manufacturers—specifically, to Mylan Pharmaceuticals Inc. ("Mylan") between 2009 and 2014; Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009; Watson Laboratories, Inc. ("Watson") in 2009; Teva Pharmaceuticals USA ("Teva") in 2009; and Sandoz Inc. ("Sandoz") in 2012. (Humana Am. Compl. ¶¶ 114, 148, 205, 211, 215 & 221; MSP SAC ¶¶ 119, 154, 217, 223, 227 & 233). More specifically, according to the Insurer Plaintiffs and MSP Plaintiffs, Mylan, Dr. Reddy's, Watson, Teva, and Sandoz sought to develop generic versions of Revlimid and requested that Celgene provide them with samples of Revlimid to use in their bioequivalency studies. (Humana Am. Compl. ¶¶ 148, 205, 211, 215 & 221; MSP SAC ¶¶ 153–54, 217, 223, 227 & 233). The Insurer Plaintiffs and MSP Plaintiffs allege that Celgene refused to provide any Revlimid samples, claiming that providing such samples would violate its REMS

MSP brings allegations regarding Celgene's alleged refusal to provide its generic competitors with samples of Thalomid.

distribution program and pose safety concerns. (*See, e.g.*, Humana Am. Compl. ¶¶ 148–55, 206–10, 213, 218 & 224; MSP SAC ¶¶ 154–62, 218–21, 225, 230 & 234–36). Celgene further stated that it was under no obligation to provide samples, sent out conclusory denials, or issued information requests for reconsideration. (*See, e.g.*, Humana Am. Compl. ¶¶ 148–55, 206–10, 213, 218 & 224; MSP. SAC ¶¶ 154–62, 218–21, 225, 230 & 234–36). In an attempt to combat Celgene's reliance on its REMS distribution program as a basis for refusal, Mylan received FDA approval of its proposed safety protocols so that it could purchase Revlimid samples even though FDA approval was allegedly not necessary for a competitor to purchase samples to test for bioequivalence. (Humana Am. Compl. ¶¶ 153–55; MSP SAC ¶¶ 159–63).[5] Further, Dr. Reddy's, Watson, and Teva allegedly provided Celgene with assurances that the process by which they would handle Revlimid would fully comply with a restricted distribution program similar to RevAssist. (Humana Am. Compl. ¶¶ 207, 212, 217–18 & 224; MSP SAC ¶¶ 219, 224, 229). Nevertheless, Celgene allegedly continued to refuse to sell any of these entities samples of Revlimid. (Humana Am. Compl. ¶¶ 155, 169, 209, 213–14, 220 & 225; MSP SAC ¶¶ 161, 175, 221, 225, 230–32 & 237).

The MSP Plaintiffs also allege that Celgene refused to sell samples of Thalomid to several generic drug manufacturers—specifically, to Mylan beginning in 2004; Lannett Company ("Lannett") in 2006; Exela Pharmsci, Inc. ("Exela") in 2006; Watson in 2009; and Sandoz in 2012. (MSP SAC ¶ 119). More specifically, according to the allegations, Mylan, Exela, Lannett, Watson, and Sandoz sought to develop generic versions of Thalomid. (*Id.* ¶¶ 127–28, 188, 195–200, 227

[5] While the Insurer Plaintiffs and MSP Plaintiffs also alleged that Sandoz received FDA approval to purchase samples of Celgene's drugs (Humana Am. Compl. ¶ 224; MSP SAC ¶ 236), following oral argument, the Insurer Plaintiffs and MSP Plaintiffs withdrew those allegations. (*In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action No. 19-7532 (D.E. No. 229); *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 223)).

& 233). The companies asked Celgene for Thalomid samples to use in their bioequivalency studies. (*Id.* ¶¶ 127–28, 188, 195–200, 227 & 233). The MSP Plaintiffs allege that Celgene refused to provide any Thalomid samples to these generic competitors, claiming that providing such samples would violate its S.T.E.P.S. distribution program and pose safety concerns for patients. (*See, e.g.*, *id.* ¶¶ 162, 193, 207, 231–32 & 236–37). Celgene also told some of the generic manufacturers that it was under no obligation to provide samples, sent out conclusory denials for any Thalomid requests, and issued information requests for reconsideration. (*See, e.g.*, *id.* ¶¶ 193, 203, 207 & 230–32). In an attempt to combat Celgene's reliance on its S.T.E.P.S. distribution program as a basis for refusal, Mylan, Lannett, and Exela received FDA approval to purchase Thalomid samples even though FDA approval was allegedly not necessary for a competitor to purchase samples to test for bioequivalence. (*Id.* ¶¶ 144–45, 191, 201–02). In fact, the MSP Plaintiffs allege that Celgene was notified of those FDA approvals, which stated that the agency would not take action if Celgene provided Thalomid samples to the generic manufacturers. (*Id.* ¶¶ 144–45, 191 & 201–02). Nevertheless, Celgene allegedly continued to refuse to provide Mylan, Lannett, and Exela with any samples of Thalomid. (*Id.* ¶¶ 144–46, 193–94 & 203). It also refused to provide Thalomid samples to Watson and Sandoz. (*Id.* ¶¶ 232 & 236). The MSP Plaintiffs further allege that in 2004 Barr Laboratories, Inc. ("Barr") succeeded in obtaining thalidomide from Seratec S.A.R.L. (*Id.* ¶ 240). Thereafter, Celgene allegedly entered into an exclusive supply agreement with Seratec S.A.R.L. to prevent Barr from obtaining thalidomide. (*Id.* ¶¶ 242–43).[6]

[6] Neither the Insurer Plaintiffs nor MSP Plaintiffs appear to bring any claims based on Celgene's conduct in entering into an exclusive supply agreement with Seratec S.A.R.L. to prevent Barr from obtaining thalidomide. (Opp. Br. at 2 n.1; Tr. of Sept. 8, 2023 Oral Arg. at 89:2–11). Regardless, in their Moving Brief, the Celgene Defendants explained how any allegations about Celgene's exclusive contract with a supplier are baseless. (Mov. Br. at 26). Those arguments went unanswered by the Insurer Plaintiffs and MSP Plaintiffs and are therefore waived. *Market v. PNC Fin. Servs. Grp.*, 828 F. Supp. 2d 765, 773 (E.D. Pa. 2011) ("Where an issue of fact or law is raised in an opening brief, but it is uncontested in the opposition brief, the issue is considered waived or abandoned by the non-movant in regard to the contested issue.").

Finally, according to the Insurer Plaintiffs and MSP Plaintiffs, despite its practice of denying generic manufacturers access to Revlimid or Thalomid samples, Celgene authorized its competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required and provided several research organizations access to Revlimid or Thalomid samples so that those research organizations could conduct clinical studies, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products. (Humana Am. Compl. ¶¶ 227–34; MSP SAC ¶¶ 252–59).

The Insurer Plaintiffs raise these allegations under Count II (Violation of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); Count VII (Unjust Enrichment Under State Law); and Count VIII (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Section 2 of the Sherman Act). (Humana Am. Compl. ¶¶ 582–87 & 600–35). The MSP Plaintiffs raise these allegations under Count I (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene and BMS's Violations of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); and Count VII (Unjust Enrichment Under State Law). (MSP SAC ¶¶ 575–82 & 627–58).

iii. The Reverse Payment and Market Allocation Allegations

Second, the Insurer Plaintiffs and MSP Plaintiffs[7] allege that Celgene entered into an anticompetitive reverse payment agreement with Natco Pharma Ltd.; Natco's U.S. Partner, Arrow

[7] In their opposition brief, filed on November 15, 2022, the MSP Plaintiffs specified that they had not alleged a viable reverse payment claim. (Opp. Br. at 3). Despite this clear concession, nearly a year later on August 18, 2023,

International Limited; and Arrow's parent company, Watson Laboratories Inc. (together "Natco")—the first-filers of an ANDA for lenalidomide—to end a then-pending patent infringement lawsuit against those companies. (Humana Am. Compl. ¶¶ 347–75 & 426–444; MSP SAC ¶ 380).[8] On August 30, 2010, Natco sent a paragraph IV certification letter to Celgene, which contained detailed factual and legal statements as to why certain patents were invalid, unenforceable, and/or not infringed by Natco's proposed generic lenalidomide. (Humana Am. Compl. ¶ 347; MSP SAC ¶ 368). Shortly thereafter, in September of 2010, Natco filed an ANDA to bring generic lenalidomide to market. (Humana Am. Compl. ¶ 348; MSP SAC ¶ 368). As the first-filer of the lenalidomide ANDA, Natco stood to benefit from a 180-day period of exclusivity, starting from the first commercial marketing of its generic lenalidomide, during which no other generic manufacturer could enter the market. (Humana Am. Compl. ¶ 341); *see* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). On October 8, 2010, Celgene filed a patent infringement suit against Natco in the District of New Jersey. (Humana Am. Compl. ¶ 349; MSP SAC ¶ 370).

On December 22, 2015, Celgene announced the settlement of its litigation with Natco. (Humana Am. Compl. ¶ 364; MSP SAC ¶ 379). Under the terms of the settlement (hereinafter the "Celgene-Natco agreement"), Celgene permitted Natco to sell its generic lenalidomide before the April 2027 expiration of Celgene's last-to-expire patent listed in the Orange Book for Revlimid. (Humana Am. Compl. ¶ 368; *see also* MSP SAC ¶ 379). Beginning in March 2022, Celgene agreed to provide Natco with a royalty-free license to sell a limited volume of generic

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the MSP Plaintiffs informed the Court that this concession in their brief was a mistake and clarified that they were in fact asserting a reverse payment claim. (Tr. of Aug. 18, 2023 Oral Arg. at 122:6–126:18).

[8] The Humana Amended Complaint refers to Natco and the partnering companies that developed and now market its generic lenalidomide product collectively as "Natco." (Humana Am. Compl. ¶ 3 n.3). According to the Insurer Plaintiffs, Natco originally partnered with Watson Pharmaceuticals, Inc., and then with Arrow. Following a series of corporate acquisitions, Teva is the current successor to, or beneficiary from, the settlement agreement between Celgene, Natco, Arrow, and Watson, and markets the ANDA product under the Teva brand name. (*Id.*).

lenalidomide. Pursuant to the agreement, the volume that Natco was permitted to sell would periodically increase until January 2026. (Humana Am. Compl. ¶¶ 366 & 368; MSP SAC ¶ 379). More specifically, during Natco's first full year of entry in 2022, Celgene allowed Natco to sell a limited amount of lenalidomide that would be capped at a mid-single digit percentage of the total lenalidomide capsules dispensed in the United States. (Humana Am. Compl. ¶ 368; MSP SAC ¶ 379). That volume limitation would increase gradually every twelve months until March of 2025, but would not exceed one third of the total lenalidomide capsules dispensed in the U.S. (Humana Am. Compl. ¶ 368; MSP SAC ¶ 379). Then, after January 2026, Natco would be permitted to sell unlimited amounts of lenalidomide. (Humana Am. Compl. ¶ 368; MSP SAC ¶ 379).

According to the Insurer Plaintiffs and the MSP Plaintiffs, the settlement between Celgene and Natco resulted in an anticompetitive reverse payment—or "pay-for-delay"—agreement. (Humana Am. Compl. ¶¶ 341 & 366; MSP SAC ¶¶ 380–81). Pay-for-delay, which often arises in the pharmaceutical patent context, is a "reverse payment" in which "a patentee pays an alleged infringer to end a lawsuit." *FTC v. AbbVie Inc.*, 976 F.3d 327, 351 (3d Cir. 2020).

> A typical reverse payment happens this way: 'Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.'

Id. (quoting *Actavis*, 570 U.S. at 140). Such agreements may be unlawful because two competitors agree not to compete and thereby unlawfully and unreasonably allocate market power. *Id.* at 351–52. A reverse payment need not necessarily be in cash form. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403–09 (3d Cir. 2015). An agreement may still be an unlawful "reverse payment" where it involves an unexplained large transfer of value from the patent holder to the alleged infringer. *Id.* at 409. Here, the Insurer Plaintiffs and MSP Plaintiffs

allege that Celgene transferred value—that was large and unexplained—to Natco in a number of ways. Because the Insurer Plaintiffs' and MSP Plaintiffs' reverse payment allegations are distinct the Court will outline them in turn.

The Insurer Plaintiffs' Reverse Payment and Market Allocation Allegations. The Insurer Plaintiffs allege that the settlement agreement between Celgene and Natco comprised both (i) an unlawful reverse payment as well as (ii) an unlawful market allocation agreement. The Court details these allegations in turn.

First, the Insurer Plaintiffs allege that the settlement agreement between Celgene and Natco comprised a two-pronged in-kind reverse payment. According to the Insurer Plaintiffs, the first prong of the reverse payment included a volume limited, royalty-free generic license before full generic competition began, equating to hundreds of millions of dollars in payment to Natco. (Humana Am. Compl. ¶ 341). The Insurer Plaintiffs allege that this volume-limited license gave Natco no incentive to compete on price and ensured that Natco's capped level sales could not effectuate bona fide downward generic price pressure, keeping prices for both Revlimid and generic lenalidomide at supracompetitive levels. (*Id.* ¶¶ 419–25). As such, the Insurer Plaintiffs allege that the royalty free, volume-limited license constituted a reverse payment because, under the agreement, Natco would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise could with no volume cap. (*Id.* ¶¶ 419–438). Further, because Celgene's brand Revlimid could retain whatever share of the market Celgene did not allocate to Natco, the Insurer Plaintiffs allege that the volume-limited license disincentivized Celgene from launching its own AG. (*Id.* ¶¶ 441–44). As the Insurer Plaintiffs explain, typically in a competitive environment, a brand manufacturer is motivated to launch an AG to limit the number of unit sales that it loses to the first generic entrant. (*Id.* ¶ 441). They allege that a volume-limited license, however, destroys

the incentive for a brand to launch its own AG because the brand has already capped the number of pills the generic can sell. (*Id.* ¶ 443). As such, the Insurer Plaintiffs contend that the volume-limited license functionally operated as a promise by Celgene not to launch its own AG. (*Id.* ¶ 443; Opp. Br. at 19). The Insurer Plaintiffs allege that this functional no-authorized generic promise constituted a reverse payment because it transferred profits Celgene would have made from its AG to Natco and ensured that Natco would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise would were it competing with an AG. (Humana Am. Compl. ¶¶ 437–38 & 441–43). The Insurer Plaintiffs allege that Natco's royalty-free volume limited license resulted in a substantial reverse payment to Natco estimated to be $3.6 billion. (*Id.* ¶¶ 427–31).

According to the Insurer Plaintiffs, the second prong of the reverse payment included an MFE or acceleration clause which both deterred later-filing generics from challenging Celgene's patents through judgment and induced Natco to accept a later entry date by eliminating the risk that Natco loses its lucrative 180-day period of exclusivity. (*Id.* ¶ 341). Under the terms of the settlement agreement, Natco could not begin selling its generic lenalidomide until March 2022. (*Id.* ¶ 368). The MFE clause, however, permits Natco to enter the market earlier, if a later (non-settling) generic is successful in invalidating Celgene's unexpired patents. (*Id.* ¶¶ 432–33). As the first-filer of the lenalidomide ANDA, Natco was entitled to a 180-day period of exclusivity, from the first commercial marketing of its drug, during which no other generic manufacturer could enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). A first-filer, however, can forfeit this exclusivity period if it fails to launch within 75 days of a court entering a final decision that the relevant patents are invalid. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). In other words, if another generic manufacturer later defeated Celgene's Revlimid patents, Natco would have 75 days to launch or

else forfeit its exclusivity. (Humana Am. Compl. ¶ 433). The MFE clause ensured Natco that it could enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement, if a later (non-settling) generic were successful in invalidating Celgene's unexpired patents. (*Id.* ¶¶ 432–33). As such, the Insurer Plaintiffs allege that the MFE clause would allow Natco to launch early in the event the patents were invalidated and retain its 180-day period of exclusivity, which was extremely valuable to Natco. (*Id.*). Further, the Insurer Plaintiffs allege that the MFE clause provided value to Natco because it disincentivized later generics from challenging the Revlimid patents. (*Id.* ¶ 432). According to the Insurer Plaintiffs, if a later (non-settling) generic were to continue the litigation and invalidate Celgene's patents, triggering the MFE clause, it would allow at least Natco to enter the market early, cutting into the non-settling generic's market share. (*Id.*). "In other words, the challenger would bear 100% of the cost and risk associated with continuing the patent challenge but would enjoy only a fraction of the rewards if it were to succeed." (*Id.*). As such, the Insurer Plaintiffs allege that the MFE clause deterred patent challenges and provided a reverse payment to Natco in the form of an assurance that it would receive the most-favorable entry date. (*Id.*).

The Insurer Plaintiffs additionally allege that Celgene settled at least four later patent infringement suits against generic companies on terms that served to preserve the "ill-gotten" gains Natco was afforded under its reverse payment agreement with Celgene. (Humana Am. Compl. ¶ 376). More specifically, the Insurer Plaintiffs allege that Celgene settled lawsuits with Dr. Reddy's; Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, "Alvogen"); Cipla Ltd. ("Cipla"); and Sun Global FZE, Sun Pharma Global Inc., Sun Pharmaceuticals Industries, Inc., and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), such that none of those generics could enter the market before the March 2022 date agreed to in the Celgene-Natco

agreement, ensuring that Natco would receive the most favorable entry date. (*Id.* ¶¶ 376–417). In exchange for ending those patent litigations, Celgene allegedly carved out a portion of its monopoly to share with Dr. Reddy's, Alvogen, Cipla, and Sun by granting them volume-limited licenses to sell generic lenalidomide after the March 2022 date provided to Natco. (*Id.*). While the Insurer Plaintiffs do not challenge these later agreements as anticompetitive reverse payment settlements (*Id.* ¶ 571 n. 214),[9] they allege that those later agreements served to shore up the anticompetitive terms (and the attendant windfall of profits) of the reverse payment agreement entered into between Celgene and Natco. (*Id.* ¶ 376).

Second, the Insurer Plaintiffs also allege that, separate and apart from their reverse payment theory, the Celgene-Natco agreement amounted to an unlawful market allocation agreement. (*Id.* ¶ 418). More specifically, the Insurer Plaintiffs allege that from when the agreement was reached in late 2015 and until early 2022, Natco agreed to delay coming to market with any generic lenalidomide, thereby allocating the entire lenalidomide market to Celgene until early 2022. (*Id.* ¶¶ 368, 434–44). Then, starting in March 2022, Natco would be allocated a small number of generic lenalidomide sales. (*Id.* ¶ 368). While the Insurer Plaintiffs do not challenge other agreements as anticompetitive (*id.* ¶ 571 n.214), they allege that Celgene's complementary agreements with other generics, including Dr. Reddy's, Alvogen, Cipla, and Sun created an anticompetitive market division. (*Id.* ¶¶ 376, 397, 408, 416 & 434–40). According to the Insurer Plaintiffs, this market allocation eliminated the incentive to compete on price, ensuring that prices of lenalidomide would remain supracompetitive even after generic entry. (Opp. Br. at 22).

[9] Though the Humana Amended Complaint provides that it believes that Celgene likely induced pay-for-delay agreements with numerous other generic manufacturers, the Amended Complaint states that "Humana can only make well-founded allegations as to Natco given the available public information. Humana reserves the right to detail additional pay-for-delay agreements, and/or name additional defendants, with the benefit of discovery." (Humana Am. Compl. ¶ 571 n.214).

The Insurer Plaintiffs raise these allegations under Count I (Violation of Section 1 of the Sherman Act); Count II (Violation of Section 2 of the Sherman Act); Count III (Conspiracy and Combination in Restraint of Trade Under 28 State Statutes); Count IV **(**Monopolization and Monopolistic Scheme under 28 State Statutes); Count V (Attempted Monopolization under 29 State Statutes); Count VI (Unfair and Deceptive Trade Practices under 36 State Statutes); Count VII (Unjust Enrichment Under State Law); and Count VIII (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Sections 1 and 2 of the Sherman Act). (Humana Am. Compl. ¶¶ 570–635).

The MSP Plaintiffs' Reverse Payment Allegations. Unlike the Insurer Plaintiffs, the MSP Plaintiffs only allege that the settlement agreement between Celgene and Natco constituted an unlawful reverse payment because it provided Natco with a volume-limited license. (MSP SAC ¶ 380). According to the MSP Plaintiffs, the volume-limited nature of the license functions as a "no authorized generic" provision "because it restricts Celgene's ability to launch its own generic—thereby establishing a *quid pro quo* relationship where the generic [] (i.e. Natco) decreases competition in the generic brand market (by eliminating Celgene's ability to launch its own generic brand) in exchange for the generic brand (i.e. Natco) agreeing to stay off the market for a certain amount of years, thereby enabling Celgene to maintain its monopoly and continue to charge supra-competitive prices for its drugs for however many years agreed upon." (*Id.*). The MSP Plaintiffs raise no allegations regarding the royalty-free nature of the license or the MFE clause to support their reverse payment allegations as to the Celgene-Natco agreement. (Tr. of Aug. 18, 2023 Oral Arg. at 125:11–19). Nor do they allege that, separate and apart from their reverse payment theory, the Celgene-Natco agreement amounted to an unlawful market allocation agreement. (*Id.* at 258:15–24).

At oral argument, the MSP Plaintiffs clarified for the first time that they are also bringing claims based on their allegations that Celgene entered into anticompetitive reverse payment settlement agreements with Barr, Lannett, Dr. Reddy's, Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, "Zydus"), and Cipla. (*Id.* at 223:22–224:2 (citing MSP SAC ¶¶ 39, 47, 214, 356–60, 366–80, 387, 392, 405, 411 & 418)). As to Barr, the MSP Plaintiffs allege that Barr filed an ANDA with the FDA for a generic version of Thalomid in September 2006 and Celgene filed an infringement lawsuit against Barr in 2007. (MSP SAC ¶¶ 346–47). On May 5, 2010, the parties settled. (*Id.* ¶ 356). According to the MSP Plaintiffs, the settlement's terms "likely . . . included a reverse payment agreement from Celgene to Barr." (*Id.* ¶ 357). Likewise, as to Lannett, the MSP Plaintiffs allege that after Lannett sued Celgene, asserting violations of the Sherman Act based on Celgene's refusals to provide Lannett with samples of Thalomid (*id.* ¶ 211), Lannett and Celgene entered into a confidential settlement "that contained anticompetitive terms, such as a promise to delay submission of an ANDA." (*Id.* ¶ 214). Likewise, the MSP Plaintiffs allege that after Lannett filed its ANDA to gain approval to market its generic version of Thalomid, Celgene filed suit against Lannett in 2015. (*Id.* ¶¶ 361–62). They allege that Celgene and Lannett entered into a settlement in 2017, which delayed the entry date of Lannett's thalidomide product. (*Id.* ¶ 366). As to Zydus, the MSP Plaintiffs allege that in 2017 Celgene filed a patent infringement suit against Zydus after Zydus filed an ANDA with the FDA for lenalidomide. (*Id.* ¶ 400). In March 2021, the parties settled. (*Id.* ¶ 405). According to the MSP Plaintiffs, the settlement's terms "likely contained anticompetitive provisions amounting to a 'pay-for-delay' agreement." (*Id.*). The MSP SAC is entirely devoid of any allegations as to why Celgene's agreements with Barr, Lannett, and Zydus amounted to an anticompetitive reverse payment.

Next, as to Dr. Reddy's the MSP Plaintiffs allege that in October 2016 Celgene filed a patent infringement suit against Dr. Reddy's after Dr. Reddy's filed its ANDA for lenalidomide. (*Id.* ¶ 383). According to the MSP Plaintiffs, the parties' settlement agreement amounted to another unlawful reverse payment agreement. (*Id.* ¶ 387). Specifically, under the terms of the agreement, Celgene agreed to provide Dr. Reddy's with a license to sell volume-limited amounts of lenalidomide sometime after March 2022. (*Id.*). Then after January 31, 2026, Dr. Reddy's could market unlimited quantities of generic lenalidomide. (*Id.*). Further, they assert that under the agreement, "Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched." (*Id.*). According to the MSP Plaintiffs, this agreement amounted to a reverse payment because it protects the vast majority of Celgene's Revlimid prescription base from generic competition and gave Dr. Reddy's little to no incentive to lower its price because it cannot gain additional market share. (*Id.*). As to Cipla, the MSP Plaintiffs allege that in 2017, 2018, and 2019, Celgene filed a patent infringement suit against Cipla after Cipla filed its ANDA for generic lenalidomide. (*Id.* ¶¶ 413–14, 419 & 423). According to the MSP Plaintiffs, the parties' settlement agreement amounted to another unlawful reverse payment agreement. (*Id.* ¶ 427). Under the terms of the agreement, Celgene agreed to provide Cipla with a license to sell volume-limited amounts of generic lenalidomide sometime after March 2022. (*Id.*). Then after January 31, 2026, Cipla could market unlimited quantities of generic lenalidomide. (*Id.*). Further, they assert that under the agreement, "Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched." (*Id.*). According to the MSP Plaintiffs, this agreement amounted to a reverse payment because it protects the vast majority of Celgene's Revlimid prescription base from generic

competition and gave Cipla little to no incentive to lower its price because it cannot gain additional market share. (*Id.*). They estimate that the value of the agreement equates to $300 million. (*Id.*).[10]

The MSP Plaintiffs raise their reverse payment allegations under Count I (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene and BMS's Violations of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); and Count VII (Unjust Enrichment Under State Law). (MSP SAC ¶¶ 575–82 & 627–58).

iv. The *Walker Process* Fraud Allegations

Third, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene fraudulently obtained some of its patents covering Revlimid in order to extend its monopoly power over the relevant market for that drug (the "*Walker Process* Fraud Allegations").[11] More specifically, the Insurer Plaintiffs allege that Celgene fraudulently obtained the following patents: (i) U.S. Patent No. 5,635,517 (the "'517 Patent" or "'517 Compound Patent"), which covers the composition of matter for Revlimid; (ii) patents that relate to the safe distribution of Revlimid (together "REMS patents"); and (iii) U.S. Patent No. 7,189,740 (the "'740 Patent" or "'740 Method of Treatment Patent"), which covers methods of using Revlimid to treat myelodysplastic syndromes. (Humana Am. Compl. ¶¶ 109, 259–276 & 301–321). The MSP Plaintiffs allege that Celgene fraudulently obtained the following patents: (i) the '517 Patent; (ii) the REMS patents; (iii) and U.S. Patent Numbers 7,465,800 (the "'800 Patent") and 7,855,217 (the "'217 Patent") that cover polymorphic

[10] The MSP SAC also raises conclusory allegations that Celgene entered into anticompetitive reverse payment settlement agreements with Alvogen, Sun, Hetero, and Apotex. (MSP SAC ¶¶ 436, 443, 460 & 468).

[11] Neither the Insurer Plaintiffs nor the MSP Plaintiffs raise any allegations of *Walker Process* fraud as it relates to Celgene's patents on Thalomid. (Opp. Br. at 2 n.1; Tr. of Sept. 8, 2023 Oral Arg. at 87:1–5).

forms of Revlimid. (MSP SAC ¶¶ 264–66, 270 & 272–342).[12] The Insurer Plaintiffs and MSP Plaintiffs then allege that Celgene asserted those fraudulently obtained patents against its competitors through sham litigation to stymy competition. (Humana Am. Compl. ¶¶ 337–539; MSP SAC ¶¶ 367–469). The Court will outline the allegations related to these patents in turn.

a. The '517 Patent

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that Celgene intentionally misrepresented and omitted material facts before the USPTO to obtain the '517 Compound Patent, which covers the composition of matter for Revlimid. (Opp. Br. at 28–31). The '517 Compound Patent has ten claims. (Humana Am. Compl. ¶ 260). Claims 1–9 cover methods of use as to six compounds, and Claim 10 covers four compounds, including lenalidomide. (*Id.*). The Insurer Plaintiffs allege that after the '517 Patent was issued, Celgene filed a request for reexamination concerning the '517 Patent with the USPTO because of a question raised by a non-adversarial third party as to the significance of certain prior art. (*Id.* ¶ 261).[13] More specifically, Celgene sought reexamination of all ten claims of the '517 Patent in view of the following prior art references: (i) D'Amato, U.S Patent No. 5,593,990; (ii) D'Amato, U.S. Patent No. 5,629,327; (iii) D'Amato, U.S. Patent No. 5,712,291 (together, "the D'Amato

[12] While the MSP Plaintiffs initially asserted that their allegations of *Walker Process* fraud were aligned with the Insurer Plaintiffs' allegations of *Walker Process* fraud, including with respect to Celgene's Method of Treatment Patents (Tr. of Sept. 8, 2023 Oral Arg. at 13:18–25), the MSP Plaintiffs later clarified that they are not asserting *Walker Process* fraud with respect to the '740 Method of Treatment Patent, which is the only method of treatment patent that the Insurer Plaintiffs claim was obtained by fraud. (*Id.* at 71:16–20; Opp. Br. at 27).

[13] Ex parte reexamination of patent validity may be requested at any time by any person upon showing that prior art exists, which consists "of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent." 35 U.S.C. §§ 301, 302. After a request for reexamination is made, the USPTO has three months to determine "whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed materials." 35 U.S.C. § 303(a). Where a reexamination is granted, it may result in cancellation of the patent as unpatentable, confirmation of the patent, or amendment of the patent. *See* 35 U.S.C. § 307. Further once the proceeding is initiated, a third party has no role in the proceeding. Only the patent holder has significant input throughout the entire process. *See Saint Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1333 (Fed. Cir. 2018).

Patents"); (iv) Leibovich et al. U.S. Patent No. 4,808,402 and (v) Leibovich et al., Macrophage-Induced Angiogenesis is Mediated By Tumor Necrosis Factor-α, Letters To Nature, Vol. 329, pages 630-632, pub. 15 October, 1987 (together, the "Leibovich References"). (*Id.*). On November 11, 1998, the USPTO granted the request for reexamination, explaining that a substantial new question of patentability affecting all ten claims of the '517 Patent was raised by the request for reexamination. (*Id.* ¶ 262). On December 9, 1998, Celgene submitted a statement to the USPTO explaining why the D'Amato Patents and Leibovich References did not render the '517 Patent invalid for obviousness. (*Id.* ¶ 263). Nevertheless, on February 22, 1999, the USPTO rejected all of the claims of the '517 Patent as obvious over the D'Amato Patents in view of the Leibovich References. (*Id.* ¶ 264).

On February 25, 1999, Celgene submitted a request for reconsideration and attached a declaration from Celgene's then Chief Scientific Officer, Dr. Stirling (the "Stirling Declaration") as support for its request. (*Id.* ¶ 265). In the declaration, Dr. Stirling explained that tests were conducted on various compounds to evaluate their relative activities, including on two compounds he identified diagrammatically and not by name—Compound 1 and Compound 2. (*Id.* ¶ 266). The Stirling Declaration explained that Compound 2 was found to be over 10,000 fold more active than Compound 1. (*Id.* ¶ 267). In its accompanying request for reconsideration, counsel for Celgene, Bruce Collins, explained Dr. Stirling's findings, stating that while Compound 1 corresponded to a compound that was disclosed in the D'Amato Patents, Compound 2 corresponded to the "amino compound of the present claims" of the '517 Patent. (*Id.* ¶¶ 268 & 276). Though Celgene maintained that the D'Amato Patents and Leibovich References did not render the claims of the '517 Patent obvious, Mr. Collins explained that even if those references were deemed sufficient to establish obviousness, any finding of obviousness was rebutted by Dr.

Stirling's Declaration, which demonstrated an unexpected property of Compound 2, in comparison to the prior art Compound 1. (*Id.* ¶ 268). Shortly thereafter, the USPTO issued a notice of intent to issue a reexamination certificate allowing the claims of the '517 Patent. (*Id.* ¶ 269).

The Insurer Plaintiffs allege that the unexpected results of Compound 2 did not pertain to any of the compounds claimed by Claim 10 of the '517 Patent. (*Id.* ¶ 270). More specifically, they allege that Compound 2 corresponded to a compound known as pomalidomide, which is only mentioned in Claim 8 of the '517 Patent as part of a method of treatment claim. (*Id.* ¶¶ 270–72). Claim 10, however, which claims four compounds, including lenalidomide, does not cover pomalidomide. (*Id.* ¶¶ 270–72). As such, because counsel for Celgene stated that Compound 2 corresponded to the "amino compound of the present claims" of the '517 Patent, the Insurer Plaintiffs allege that the Stirling Declaration misled the examiner into believing that *all of the claims* of the '517 Compound Patent were patentable, when in fact the patentability of Claim 10 could not be supported by the unexpected properties of Compound 2. (*Id.* ¶¶ 268 & 274). Also notable, the Insurer Plaintiffs allege, is that Dr. Stirling states in his declaration that he performed testing on "various compounds" but only submitted data with respect to Compounds 1 and 2. (*Id.* ¶ 273). Based on this language, they allege that Celgene concealed the rest of the data and cherrypicked the results that would best support its claim of unexpected results. (*Id.*). The Insurer Plaintiffs contend that these allegations support a finding of fraudulent conduct by Dr. Stirling who signed and submitted the declaration and "potentially" by Celgene's in-house and outside counsel who submitted the request for reconsideration and characterized Compound 2 as corresponding to the "amino compound of the present claims" of the '517 Patent. (*Id.* ¶¶ 268 & 276). They further claim that Dr. Stirling's intent to deceive the USPTO is supported by the fact that he had detailed first-hand knowledge of Celgene's compound testing programs and chose to present testing

regarding a compound other than one covered by Claim 10 of the '517 Compound Patent. (*Id.* ¶ 275). In sum, the Insurer Plaintiffs allege that the '517 Compound Patent was obtained by fraud. (*Id.* ¶¶ 274–75). Further, the Insurer Plaintiffs allege that Celgene asserted the fraudulently obtained '517 Patent against its competitors in litigation. (*See e.g., id.* ¶¶ 352 & 389).

The MSP Plaintiffs' Allegations. The MSP Plaintiffs generally allege that the '517 Patent was procured by fraud because the USPTO was not aware of key prior art when the '517 Patent was granted. (MSP SAC ¶¶ 264–65). The MSP Plaintiffs' Second Amended Complaint does not otherwise contain any allegations regarding the fraud Celgene allegedly committed during reexamination of the '517 Patent through the Stirling Declaration. Further, the MSP Plaintiffs allege that Celgene asserted the fraudulently obtained '517 Patent against its competitors in litigation. (*See e.g., id.* ¶ 368).

b. The '740 Method of Treatment Patent

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs next allege that Celgene defrauded the USPTO in obtaining the '740 Method of Treatment Patent. During the prosecution of the '740 Patent, the USPTO rejected the claims as anticipated over U.S. Application No. 03/0235909 and U.S. Application No. 04/0067953 ("Stein") and also rejected the claims as anticipated or obvious over WO 01/87307 and for double patenting over U.S. Application No. 10/438213. (Humana Am. Compl. ¶ 315). To overcome these prior art rejections, Celgene filed a declaration by Celgene's then Vice President and Chief Medical Officer Jerome Zeldis (the "First Zeldis Declaration") who was the inventor of the '740 Patent. (*Id.* ¶ 316). In the First Zeldis Declaration, Zeldis asserted that he conceived of the presently claimed invention prior to March 8, 2002—earlier than any of the prior art references the examiner relied on in rejecting the claims of the '740 Patent. (*Id.*). To support this assertion, Zeldis submitted a clinical trial protocol and

abstract, which described the studies Zeldis conducted with respect to the invention. (*Id.* ¶¶ 316–17). However, the Insurer Plaintiffs allege that neither the clinical trial protocol nor abstract contained any date information regarding when those studies took place. As such, they assert that those documents did not support Zeldis's claim that he conceived of the presently claimed invention prior to March 8, 2002. (*Id.* ¶¶ 318–19).

After Celgene filed the First Zeldis Declaration, the USPTO again rejected the claims of the '740 Patent as obvious over a newly cited prior art reference, Raza (August 2001, Blood), in view of WO 01/87307 (international publication date of November 22, 2001). (*Id.* ¶ 320). In response, Celgene submitted a second declaration from Zeldis (the "Second Zeldis Declaration"), in which Zeldis claimed that he conceived of the presently claimed invention prior to July 19, 2001—earlier than any of the newly cited prior art references the examiner relied on in rejecting the claims of the '740 Patent for a second time. (*Id.*). To support this assertion, Zeldis again referenced the clinical trial protocol and abstract as support. (*Id.*). After the Second Zeldis Declaration was submitted, the '740 Patent was granted. (*Id.*). The Insurer Plaintiffs allege that Celgene obtained the '740 Patent by fraud because Zeldis provided no support for his assertion that he conceived of the present invention before the prior art references relied on by the examiner. And further, the Insurer Plaintiffs allege that Celgene asserted that fraudulently obtained patent against its competitors in litigation. (*See, e.g.*, *id.* ¶¶ 389, 400, 460, 492, 502, 524, 530 & 534).[14]

c. The REMS Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that Celgene made fraudulent omissions to the USPTO to obtain its REMS Patents, which relate to the safe

[14] The MSP Plaintiffs' Second Amended Complaint does not contain allegations regarding Celgene's fraud in obtaining the '740 Patent.

distribution of drugs like Revlimid. (Opp. Br. at 31–32).[15] To start, The Insurer Plaintiffs point out that two of Celgene's REMS Patents, the '501 Patent and'720 Patent were invalidated by the Patent Trial and Appeal Board ("PTAB"), using logic that would render other Celgene's REMS Patents invalid as well. (Humana Am. Compl. ¶ 302). The PTAB found the '501 Patent invalid as obvious over three prior art references. (*Id.* ¶ 303). The first reference (the "Powell Reference") disclosed guidance regarding the clinical use and dispensing of thalidomide and identified a patient subpopulation of women who could and wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception. (*Id.* ¶ 304). The second reference (the "Mitchell Reference") disclosed an existing pregnancy-prevention program for women users of Accutane, which was another dangerous drug for pregnant women subject to a program of preventative measures. (*Id.* ¶ 305). The third reference (the "Dishman Reference") disclosed a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous, including a drug called Clozaril. (*Id.* ¶¶ 306–307). After considering these references, the PTAB found that the '501 Patent was invalid. (*Id.* ¶ 307). The PTAB also found that the '720 Patent was obvious over the same three references, as well as one additional prior art reference that described an approval code used by prescribers and pharmacies to track and manage

[15] The Insurer Plaintiffs appear to allege that Celgene engaged in *Walker Process* fraud with respect to the following REMS patents: U.S. Patent Numbers 6,045,501 (the "'501 Patent"); 6,315,720 (the "'720 Patent"); 6,561,976 (the "'976 Patent"); 6,561,977 (the "'977 Patent"); 6,755,784 (the "'784 Patent"); 6,869,399 (the "'399 Patent"); 7,141,018 (the "'018 Patent"); 7,959,566 (the "'566 Patent"); 8,315,886 (the "'886 Patent"); and 8,626,531 (the "'531 Patent"). (Humana Am. Compl. ¶¶ 302–12). At oral argument, they also suggested that Celgene engaged in *Walker Process* fraud with respect to U.S. Patent Nos. 8,589,188 (the "'188 Patent"), 8,204,763 (the "'763 Patent"), and 6,908,432 (the "'432 Patent). (Tr. of Sept. 8, 2023 Oral Arg. at 80:3–6). Nevertheless, there do not appear to be any specific allegations of fraud as to the '188 Patent, '763 Patent, and '432 Patent in the Insurer Plaintiffs' Amended Complaint. (*See generally* Humana Am. Compl.). Further, though the Insurer Plaintiffs appear to allege that Celgene engaged in *Walker Process* fraud with respect to the '399, '018 and '566 Patents, those patents relate to the safe distribution of Thalomid. (Humana Am. Compl. ¶ 109). As mentioned, the Insurer Plaintiffs clarified, both in their opposition brief and at oral argument, that they are neither pursuing any stand-alone claims based on Celgene's conduct related to Thalomid, nor seeking any Thalomid damages. (Opp. Br. at 2 n.1; Tr. of Aug 18, 2023 Oral Arg. at 31:10–16). As such, the Court does not consider any challenges as to the '399, '018 and '566 Patents.

pharmaceutical products. (*Id.* ¶ 308). In invalidating these patents, the PTAB noted that, when it benefited Celgene's interests before the FDA, Celgene freely admitted that its plan for the safe distribution of its drugs was based on experience with restrictions on other drugs with severe adverse effects such as Accutane and Clozaril. (*Id.* ¶ 309). The Insurer Plaintiffs allege that despite being aware of those prior art references, Celgene failed to disclose the very materials that it relied on in presenting its program to the FDA to obtain its REMS Patents. (*Id.*). As such, the Insurer Plaintiffs allege that Celgene obtained the '501 Patent and '720 Patent by fraud. Further, they note that the '976 Patent, '977 Patent;'784 Patent are nearly identical to these fraudulently obtained Patents. (*Id.* ¶ 310).

Further, the Insurer Plaintiffs allege that at least the '720 Patent, '977 Patent, '784 Patent, and '399 Patent were obtained by inequitable conduct, or fraud, because the applicants of these patents concealed from the USPTO prior art references that they knew were material to patentability with the intent to deceive the patent examiner. (*Id.* ¶¶ 310 n.103 & 311). Relatedly, the Insurer Plaintiffs allege that because four other REMS Patents including the '018 Patent; '566 Patent; '886 Patent; and '531 Patent are not sufficiently distinct from the unenforceable '720 Patent, '977 Patent, '784 Patent, and '399 Patent, they too are unenforceable under the doctrine of infectious unenforceability.[16]

The MSP Plaintiffs' Allegations. The MSP Plaintiffs also allege that Celgene made fraudulent omissions to the USPTO to obtain its REMS Patents. (Opp. Br. at 31–32).[17] To start,

[16] Pursuant to the doctrine of infectious unenforceability, inequitable conduct associated with one patent may render a related patent unenforceable. *See, e.g., Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.*, Civil Action No. 15-0137, 2017 WL 1349175, at *20 (D. Del. Apr. 10, 2017); *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F. 2d 804, 810–11 (Fed. Cir. 1990).

[17] The MSP Plaintiffs appear to allege that Celgene engaged in *Walker Process* fraud with respect to the following REMS patents: the '501 Patent, '720 Patent, '976 Patent, '784 Patent, '977 Patent, and '886 Patent. (MSP SAC ¶¶ 273–340; Tr. of Sept. 8, 2023 Oral Arg. at 80:3–22).

like the Insurer Plaintiffs, the MSP Plaintiffs point out that two of Celgene's REMS Patents, the '501 Patent and'720 Patent were invalidated by the PTAB. (MSP SAC ¶ 273). More specifically, they allege that the PTAB found the '501 Patent invalid as obvious over the Powell Reference, the Mitchell Reference, and the Dishman Reference. (*Id.* ¶¶ 275–78). The PTAB also found that the '720 Patent was obvious over the same three references, as well as one additional prior art reference. (*Id.* ¶ 279). The MSP Plaintiffs allege that despite being aware of those prior art references, Celgene failed to disclose the very materials that it relied on in presenting its program to the FDA to obtain its REMS Patents. (*Id.* ¶ 280). As such, the MSP Plaintiffs allege that Celgene obtained the '501 Patent and '720 Patent by fraud.

The MSP Plaintiffs further allege that the REMS Patents including the '501 Patent, '720 Patent, '976 Patent, '784 Patent,'977 Patent, and '886 Patent were obtained by fraud because the applicants of these patents concealed from the PTO prior art references that they knew were material to patentability with the intent to deceive the USPTO. (*Id.* ¶¶ 282–340). The prior art cited by the MSP Plaintiffs consists of procedures for the safe distribution and use of dangerous drugs, which may be grouped into three categories: (i) pharmaceutical distribution programs and packaging, (ii) publications, and (iii) meetings. The prior art cited by the MSP Plaintiffs is listed below by category:

Pharmaceutical Distribution Programs and Packaging

1. Clozaril Patient Monitoring Service ("CPMS");

2. Accutane Pregnancy Prevention Program ("PPP");

3. Accutane PPP Package ("PPP Package"), a patient and prescriber information packet for Accutane released in 1994.

Publications

> 4. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services* 47(1): 52–56 (1996) ("Honigfeld I");
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> 5. Honigfeld, *et al.*, "Reducing Clozapine–Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," *J. Clin. Psychiatry* 59 suppl. 3: 3–7 (1998) ("Honigfeld II");
>
> 6. "Guide to the Clozaril Patient Monitoring Service," ("the Guide"), which was published in 1997, and described the details of CPMS;
>
> 7. Zeldis, *et al.*, "S.T.E.P.S.: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319–30 (1999) ("Zeldis").
>
> *Meetings*
>
> 8. CDC Meeting—a Centers for Disease Control ("CDC") public meeting titled "Preventing Birth Defects Due to Thalidomide Exposure" and its corresponding transcript from March 26, 1997 ("CDC Meeting and Transcript");
>
> 9. CDER Meeting—a public meeting held by the Center for Drug Evaluation and Research of the FDA on September 4 and 5, 1997 ("CDER Meeting and Transcript");
>
> 10. NIH Meeting—a public workshop held on September 9 and 10, 1997, by the National Institutes of Health ("NIH"), FDA, and CDC entitled "Thalidomide: Potential Benefits and Risks Open Scientific Workshop." ("The NIH Meeting and Transcript").

(*Id.* ¶¶ 282–340). The MSP Plaintiffs contend that Bruce Williams, a Celgene employee and the named inventor of some of the REMS Patents, and Dr. Jerome Zeldis, then-Vice President of Medical Affairs at Celgene, attended the CDC Meeting in March 1997 at which CPMS and PPP were discussed as foundations for developing similar distribution methods and controls for thalidomide. (*Id.* ¶¶ 303–07). Further, the MSP Plaintiffs go on to assert that later that same year, Williams gave presentations at both the CDER meeting and NIH meeting regarding the creation of a distribution and control program for thalidomide and referenced both CPMS and PPP. (*Id.* ¶¶

313–24). The MSP Plaintiffs also assert that Zeldis and Williams, along with other Celgene employees, authored and published the Zeldis Article in 1999, which describes S.T.E.P.S. and acknowledges that the program was based on experience gained from other drugs such as Clozaril. (*Id.* ¶¶ 308–11). According to the MSP Plaintiffs, the Zeldis Article also cites to Honigfeld I and II. (*Id.* ¶ 311). The MSP Plaintiffs allege that Celgene was aware of all of this prior art but failed to disclose it to the USPTO during the prosecution of its relevant REMS Patents. (*Id.* ¶¶ 282–340). According to the MSP Plaintiffs, the omission of these prior art materials constitutes fraud on the USPTO. (*Id.* ¶¶ 282–340).

d. The Polymorph Patents

The MSP Plaintiffs' Allegations. Finally, the MSP Plaintiffs also generally allege that two of Celgene's polymorph patents,[18] including the '800 Patent and '217 Patent were obtained by fraud because Celgene failed to disclose available prior art and research from decades earlier when obtaining those patents. (*Id.* ¶ 270). The MSP Plaintiffs do not otherwise elaborate on these allegations.

The Insurer Plaintiffs raise their fraud allegations under Count II (Violation of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); Count VII (Unjust Enrichment Under State Law); and Count VIII (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Section 2 of the Sherman Act). (Humana Am. Compl. ¶¶ 570–635). The MSP Plaintiffs raise their fraud allegations under Count I (Declaratory and Injunctive Relief Under Section 16 of the

[18] Polymorphism refers to the ability of a compound to form with different crystal structures. (Humana Am. Compl. ¶ 287). "Although the different polymorphic forms of a compound will have the same chemical composition, the differences in crystalline structure impact the compound's chemical properties, such as solubility and bioavailability." (*Id.*).

Clayton Act for Celgene and BMS's Violations of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); and Count VII (Unjust Enrichment Under State Law). (MSP SAC ¶¶ 575–82 & 627–58).

v. The Sham Litigation Allegations

Fourth, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene brought sham patent infringement lawsuits against various generic competitors to enforce patents that were unenforceable, invalid, and/or not infringed including its (i) '517 Compound Patent; (ii) method of treatment patents; (iii) polymorph patents; and (iv) REMS Patents (the "Sham Litigation Allegations"). (Humana Am. Compl. ¶¶ 251–539; MSP SAC ¶¶ 264–469).[19] Further, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene filed sham lawsuits asserting patents that were not listed in the Orange Book. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). Celgene allegedly filed sham lawsuits against the following companies that filed lenalidomide ANDAs: Natco in 2010; Dr. Reddy's in 2016, 2017, and 2018; Zydus in 2017 and 2018; Cipla in 2017, 2018 and 2019; Alvogen in 2017 and 2018; Apotex Inc. ("Apotex") in 2018 and 2019; Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero Drugs Ltd., and Hetero USA, Inc. (collectively, "Hetero") in 2018, 2019 and 2020; Sun in 2018; Mylan in 2019 and 2020; Lupin Ltd. ("Lupin") in 2020 and 2021; Hikma Pharmaceuticals USA, Inc. ("Hikma") in 2021; Aurobindo Pharma Ltd., Eugia

[19] Though the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene delayed Barr's generic thalidomide product through a 2007 petition to the FDA (Humana Am. Compl. ¶ 331; *see also* MSP SAC ¶ 347), both the Insurer Plaintiffs and the MSP Plaintiffs clarified that they are not raising any allegations of sham litigation as it relates to Celgene's patents on Thalomid. (Opp. Br. at 2 n.1; Tr. of Sept. 8, 2023 Oral Arg. at 89:2–11). Regardless, in their Moving Brief, the Celgene Defendants explained how any allegations about Celgene's 2007 petition are baseless. (Mov. Br. at 26). Those arguments went unanswered by the Insurer Plaintiffs and MSP Plaintiffs and are therefore waived. *Market*, 828 F. Supp. 2d at 773.

Pharma Specialties Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo") in 2021; Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent") in 2021; Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. (collectively, "Biocon") in 2021; and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic") in 2021. (Humana Am. Compl. ¶ 344; *see also* MSP SAC ¶ 344).[20] The Court will outline the sham litigation allegations related to the aforementioned patents in turn.

a. The '517 Patent

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because (i) its fraudulent conduct would render the patent unenforceable; (ii) the patent is invalid as obvious; and (iii) the patent is invalid as not enabled based on testing by Celgene described in a declaration submitted to the European Patent Office ("EPO"). (Opp. Br. at 36–37).

First, as described above, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on the '517 Patent because its fraudulent conduct during the reexamination of that patent would render the patent unenforceable. (*Id.* at 36). More specifically, the Insurer Plaintiffs reference their allegations, described above, that Celgene misled the USPTO during reexamination through the Stirling Declaration. (Humana Am. Compl. ¶¶ 259–76).

Second, the Insurer Plaintiffs allege that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because the patent is invalid as obvious in light

[20] The MSP Plaintiffs' Second Amended Complaint does not contain allegations regarding sham lawsuits against Mylan, Hikma, Aurobindo, Torrent, Lupin, Biocon or Alembic.

of research conducted before the '517 Patent's priority date. (Opp. Br. at 36). To start, the Insurer Plaintiffs allege that the '517 Patent is obvious over the D'Amato Patents and Leibovich References that caused the examiner to revoke the '517 Patent during reexamination. (Humana Am. Compl. ¶¶ 259–74). The Insurer Plaintiffs further allege that Claim 10 of the '517 Patent—which claimed lenalidomide—would have been obvious in light of two compounds that were disclosed in the prior art, namely EM-12 and/or 4-aminothalidomide. They claim that these compounds were structurally similar to lenalidomide and were known to treat a variety of conditions. (*Id.* ¶¶ 252–58). The Insurer Plaintiffs allege that a person of ordinary skill in the art would have been motivated to make small structural changes to these compounds, yielding the lenalidomide compound claimed by the '517 Patent and rendering it obvious. (*Id.*).

Third, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail on its claims that the '517 Patent was valid because the patent is invalid as not enabled based on testing Celgene described in a declaration submitted to the EPO. On November 2, 2011, the EPO granted Celgene European Patent ("EP") Number 1,667,682, ("EP '682"), a patent that covered a polymorphic form of lenalidomide. (*Id.* ¶ 288). On January 8, 2012, Mylan filed a Notice of Opposition with the EPO requesting that the EPO revoke EP '682 as lacking novelty in light of Celgene's (US) '517 Compound Patent. (*Id.* ¶ 290). Mylan asserted that, if the steps in Example 1 of the '517 Patent are carried out, it results in the same polymorphic form of lenalidomide claimed by EP '682, rendering EP '682 invalid as anticipated. (*Id.*). Teva filed a similar notice of opposition, which included similar testing results. (*Id.* ¶ 291). On March 9, 2015, Celgene filed the declaration of Dr. Natarajan in an attempt to counter the testing results submitted by Mylan and Teva. (*Id.* ¶ 292). Dr. Natarajan explained that he "was asked to synthesize . . . lenalidomide, by exactly following the procedures of . . . Example 1 of U.S. Patent No. 5,635,517."

(*Id.*). According to the Insurer Plaintiffs, rather than providing support for Celgene's argument that EP '682 was not anticipated, Celgene's own expert actually presented results that cast doubt on the validity of the '517 Patent. (*Id.*). More specifically, in his sworn declaration, Dr. Natarajan reported that when he followed the procedures of Example 1 of the '517 Patent, he did not obtain lenalidomide (polymorph or otherwise) ***at all***. (*Id.*). As such, the Insurer Plaintiffs allege that the data presented by Celgene's expert to the EPO supports the argument that the '517 Patent lacks enablement and is therefore invalid. (*Id.*).[21]

The MSP Plaintiffs' Allegations. The MSP Plaintiffs allege that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because (i) its fraudulent conduct would render the patent unenforceable; (ii) and the patent is invalid as obvious. (Opp. Br. at 36–37).

First, the MSP Plaintiffs also allege that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on the '517 Patent because that patent was procured by fraud. However, to support their contention that the '517 Patent was procured by fraud, the MSP Plaintiffs merely allege that the USPTO was not aware of key prior art when the '517 Patent was granted. (MSP SAC ¶¶ 264–65). Second, the MSP Plaintiffs' Second Amended Complaint only generally alleges that the'517 Patent is obvious in light of innovations and research conducted long before Celgene began its effort to bring Thalomid and Revlimid to the market. (*Id.*).

b. The Method of Treatment Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs next allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to certain of its method of treatment patents because: (i) the '740 Method of Treatment Patent is

[21] The MSP Plaintiffs' Second Amended Complaint does not contain any similar allegations.

unenforceable due to fraud and invalid as obvious in light of prior art, which also renders two of Celgene's other method of treatment patents invalid including U.S. Patent Numbers 8,404,717 (the "'717 Patent") and 9,056,120 (the "'120 Patent"); and (ii) the patents claiming methods of treating cancer, including U.S. Patent Numbers 7,968,569 (the "'569 Patent"), 8,530,498 (the "'498 Patent"), 8,648,095 (the "'095 Patent"), and 9,101,622 (the "'622 Patent") are obvious based on prior art. (Opp. Br. at 38).

To start, as described above, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on the '740 Method of Treatment Patent because its fraudulent conduct during the prosecution of that patent would render the patent unenforceable. (Opp. Br. at 38). More specifically, the Insurer Plaintiffs rely on their allegations, discussed earlier, that Celgene obtained the '740 Method of Treatment Patent by fraud because inventor, Zeldis, provided no support for his assertion that he conceived of the invention disclosed in the '740 Method of Treatment Patent before the prior art references relied on by the examiner in rejecting the patent. (Humana Am. Compl. ¶¶ 313–21). As such, because the '740 Method of Treatment Patent was allegedly procured by fraud, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail on its claims asserting that patent.[22]

Further, the Insurer Plaintiffs allege that because Celgene obtained the '740 Method of Treatment Patent by fraud, that patent is also invalid as obvious over the prior art references relied on by the examiner in initially rejecting the patent, including U.S. Application No. 03/0235909 and U.S. Application No. 04/0067953 ("Stein"), WO 01/87307, Raza (August 2001, Blood), and WO 01/87307 (international publication date of November 22, 2001). (*Id.* ¶¶ 315 & 320).[23]

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[22] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations.

[23] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations.

Next, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to certain of its method of treatment patents because the patents claiming methods of treating cancer are obvious based on prior art. (Opp. Br. at 38). More specifically, they allege that Celgene's multiple myeloma method of treatment patents including the '569 Patent, '498 Patent, '095 Patent, and '622 Patent, which claim the administration of lenalidomide in combination with a steroid called dexamethasone in specific dosing regimens, are subject to strong invalidity challenges, including obviousness. (Humana Am. Compl. ¶ 327; Tr. of Sept. 8, 2023 Oral Arg. at 158:15–21). The Insurer Plaintiffs claim that it was well known in the prior art before May 17, 2002—the priority date of some of the method of treatment patents—that lenalidomide in combination with steroids such as dexamethasone could be used to treat cancers. (Humana Am. Compl. ¶¶ 327–28). The Insurer Plaintiffs allege that during prosecution, to overcome the USPTO's rejections for obviousness based on those prior art references, Celgene submitted findings it argued showed that it had determined, before the date of its May 2002 application, that there were unexpected results in the administration of lenalidomide in combination with dexamethasone in specific dosing regimens. (*Id.* ¶ 328). However, according to the Insurer Plaintiffs, Celgene's unexpected results either were not, in fact, unexpected or post-dated the claimed invention by a significant period of time. (*Id.*). For example, during the prosecution of the '569 Patent, Celgene allegedly submitted numerous publications to show that its claimed method of treatment had surprising and unexpected effects in treating multiple myeloma patients in comparison to the prior art. (*Id.*). However, because the publications submitted to show those unexpected results post-dated the claimed invention, the Insurer Plaintiffs assert that they did not support a finding of patentability at the time of the invention. (*Id.* ¶ 329).[24]

[24] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations.

The MSP Plaintiffs' Allegations. While the MSP Plaintiffs generally allege that Celgene's conduct in asserting certain of its Method of Treatment Patents was a sham, they provide no allegations to explain why no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the method of treatment patents. (*See, e.g.*, MSP SAC ¶¶ 367–469; Tr. of Sept. 8, 2023 Oral Arg. at 151:15–152:9).

c. The Polymorph Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail on its infringement allegations as to its polymorph patents because: (i) U.S. Patent Numbers 7,977,357 (the "'357 Patent"), 8,431,598 (the "'598 Patent"), and 8,193,219 (the "'219 Patent") were invalid as anticipated or obvious; and (ii) the '800 Patent and '217 Patent were invalid as anticipated or obvious and invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40).

First, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its polymorph patents because the '357 Patent, '598 Patent, and '219 Patent were invalid as anticipated or obvious. More specifically, the Insurer Plaintiffs allege that Celgene's filings in other proceedings, such as in defending its European polymorph patent, EP '682 before the EPO, indicate that the '357 Patent, '598 Patent, and '219 Patent are invalid. According to the Insurer Plaintiffs, on November 2, 2011, the EPO granted Celgene EP '682. (Humana Am. Compl. ¶ 288). Claim 14 of EP '682 claims a polymorphic form of lenalidomide having an X-ray powder diffraction pattern[25] with peaks at approximately 8, 14.5, and 16 degrees 2θ. (*Id.*). Celgene defines the lenalidomide polymorph

[25] Polymorphic forms are identified by their particular X-ray powder diffraction pattern, with peaks at specified locations. (Humana Am. Compl. ¶ 287).

with peaks at these locations as "Form A." (*Id.*). According to the Insurer Plaintiffs, Celgene's U.S. Polymorph Patents, including the '357 Patent, '598 Patent, and '219 Patent, also claimed Form A of the lenalidomide polymorph. (*Id.* ¶ 289). As recounted above, on January 8, 2012, Mylan filed a Notice of Opposition with the EPO requesting that the EPO revoke Celgene's European Patent, EP '682, as lacking novelty in light of Celgene's (US) '517 Patent. (*Id.* ¶ 290). Mylan asserted that, if the steps in Example 1 of the '517 Patent are carried out, it results in the same Form A lenalidomide polymorph as claimed by EP '682, rendering EP '682 invalid as anticipated. (*Id.*). On February 8, 2012, Teva filed a Notice of Opposition similarly requesting the revocation of EP '682 on the basis of lack of novelty in light of the '517 Patent. (*Id.* ¶ 291). As with Mylan, Teva's experts carried out Example 1 of the '517 Patent and reported that it resulted in the same Form A lenalidomide polymorph as claimed by EP '682. (*Id.*). To defend the validity of its European Patent, Celgene filed a declaration, asserting that when Celgene's own expert was asked to synthesize lenalidomide by following the procedures of Example 1 of the '517 Patent he did not obtain lenalidomide at all. (*Id.* ¶ 292). As such, Celgene argued that its European polymorph patent could not be anticipated by its U.S. '517 Patent. (*Id.*). On June 24, 2015, the EPO issued a decision revoking EP '682 based on the rationale that Form A claimed by EP '682 was anticipated by the '517 Patent. (*Id.* ¶ 293). In so holding, the EPO remarked on Celgene's failure to present evidence to rebut Mylan and Teva's testing results, which indicated that following the teachings of the '517 Patent inevitably leads to Form A of lenalidomide as claimed by EP '682. (*Id.*). Because the '357 Patent, '598 Patent, and '219 Patent also claim Form A of the lenalidomide polymorph, the Insurer Plaintiffs allege that the '357 Patent, '598 Patent, and '219 Patent are also invalid as anticipated or obvious based on the '517 Patent. (*Id.* ¶ 294).[26]

[26] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations. (*See* Tr. of Sept. 8, 2023 Oral Arg. at 161:23–162:2).

Second, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its polymorph patents because the '800 Patent and '217 Patent are invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40). More specifically, the Insurer Plaintiffs allege that based on Celgene's own representations regarding the interpretation of claims in the '800 Patent and '217 Patent in a *Markman* hearing that was held in a litigation against Natco, the claims of the patents are invalid as overbroad. (Humana Am. Compl. ¶ 300). According to the Insurer Plaintiffs, the '800 Patent and '217 Patent claim polymorph embodiments of lenalidomide. (*Id.* ¶ 355). Polymorph embodiments may differ based upon their level of solvation or hydration. (*Id.*). As such, certain polymorphs can be "unsolvated" or "hemihydrated." (*Id.*). The '800 Patent includes the term "hemihydrate" to describe its claimed polymorphic form of lenalidomide. (*Id.* ¶ 358). After Celgene asserted the '800 Patent against Natco in litigation, Natco argued that the term "hemihydrate" as appearing in the '800 Patent required an exact water-to-compound ratio of 0.5 to 1. (*Id.*). Celgene, by contrast, argued that "hemihydrate," as used in the patent, implied an *approximate,* rather than exact, ratio. (*Id.*). In the court's *Markman* Opinion, the court adopted Celgene's proposed definition, reading "hemihydrate," as a term of approximation. (*Id.* ¶ 359). Less than a month after the *Markman* hearing, Natco moved to amend its defenses, arguing invalidity for indefiniteness, lack of written description, and lack of enablement. (*Id.* ¶ 360). Relying on this argument from the Natco litigation, the Insurer Plaintiffs allege that with the gloss of the term "approximately" applied to "hemihydrate," the '800 Patent is invalid for indefiniteness, lack of written description, and lack of enablement because (i) a person of ordinary skill would be unable to determine the scope of the patent, (ii) the patent does not disclose or suggest to a person of ordinary skill in the art that the patentee was in possession

of other hemihydrated forms of lenalidomide, and (iii) the patent does not disclose how to make other hemihydrated forms. (*Id.*). Because the '217 Patent also includes the term "hemihydrate," the Insurer Plaintiffs allege that it is invalid for the same reasons. (*Id.* ¶ 299).

Third, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because those patents are invalid as obvious and/or anticipated. (Opp. Br. at 40). More specifically, they allege that the '800 and '217 Patents were "obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent." (*Id.* ¶ 300). They further allege that "[t]hese polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity." (*Id.*). As such, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its '800 and '217 polymorph patents.

The MSP Plaintiffs' Allegations. The MSP Plaintiffs also allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its polymorph patents because the '800 Patent and '217 Patent were invalid as anticipated and/or obvious and invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40).

First, like the Insurer Plaintiffs, the MSP Plaintiffs also allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its polymorph patents because the '800 Patent and '217 Patent are invalid for failing to satisfy the definiteness, written description, and enablement requirements based on Celgene's own representations regarding the interpretation of the term "hemihydrate" as appearing in the '800 Patent and '217 Patent in a *Markman* hearing that was held in a litigation against Natco. (MSP

SAC ¶¶ 269–70, 375–77). Second, like the Insurer Plaintiffs, the MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because those patents are invalid as obvious and/or anticipated. (Opp. Br. at 40). More specifically, they allege that the '800 and '217 Patents were "obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent" and "are also obvious variants of the composition of matter patent, adding a further basis for invalidity." (MSP SAC ¶ 270). As such, the MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its '800 and '217 polymorph patents. The MSP Plaintiffs do not allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its polymorph patents because the '357 Patent, '598 Patent, and '219 Patent are invalid as anticipated or obvious. (Tr. of Sept. 8, 2023 Oral Arg. at 161:23–162:2). Rather, they merely generally allege that Celgene's conduct in asserting these patents against its competitors was a sham. (*See, e.g.*, MSP SAC ¶¶ 400–434).

d. The REMS Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its REMS Patents because: (i) it fraudulently obtained certain REMS Patents and (ii) the prior art that led the PTAB to invalidate two of Celgene's REMS patents (the '720 and '501 Patents), would also invalidate Celgene's other REMS Patents. (Opp. Br. at 37).

First, as described above (*supra* at 29–31), the Insurer Plaintiffs allege that Celgene made fraudulent omissions to the USPTO to obtain its '720 and '501 REMS Patents, which relate to the safe distribution of drugs like Revlimid. (Humana Am. Compl. ¶¶ 301–09). Further, they note

that the '976 Patent, '977 Patent and '784 Patent are nearly identical to these fraudulently obtained patents. (*Id.* ¶ 310). In addition, the Insurer Plaintiffs allege that at least the '720 Patent, '977 Patent, '784 Patent, and the '399 Patent were obtained by inequitable conduct because the applicants of these patents concealed from the USPTO prior art references that they knew were material to patentability—with the intent to deceive the patent examiner. (*Id.* ¶¶ 310 n.103 & 311). Finally, the Insurer Plaintiffs allege that because four other REMS Patents, including the '018, '566, '886, and '531 patents, are not sufficiently distinct from the unenforceable '720 Patent, '977 Patent, '784 Patent, and '399 Patent, they too are unenforceable under the doctrine of infectious unenforceability. (*Id.* ¶ 312).

Second, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its REMS Patents because the prior art that led the PTAB to invalidate two of Celgene's REMS Patents (the '720 and '501 Patents), would invalidate Celgene's other REMS Patents. (Opp. Br. at 37). As described above (*supra* at 29–31), the PTAB found the '501 Patent invalid as obvious over three prior art references, including the Powell Reference, the Mitchell Reference, and the Dishman Reference. (Humana Am. Compl. ¶¶ 304–06). The PTAB also found the '720 Patent as obvious over the same three references, as well as one additional prior art reference that described an approval code used by prescribers and pharmacies to track and manage pharmaceutical products. (*Id.*). The Insurer Plaintiffs allege that Celgene's other REMS Patents are invalid for the same reasons. (*Id.* ¶ 302).

The MSP Plaintiffs' Allegations. The MSP Plaintiffs also allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its REMS Patents because: (i) it fraudulently obtained certain REMS Patents and (ii) the prior art that led the PTAB to invalidate two of Celgene's REMS patents (the '720 and '501 Patents)

would also invalidate Celgene's other REMS Patents. (Opp. Br. at 37). First, as described above, the MSP Plaintiffs allege that Celgene made fraudulent omissions to the USPTO to obtain its '720 and '501 REMS Patents, which relate to the safe distribution of drugs like Revlimid. (MSP SAC ¶ 280). The MSP Plaintiffs also allege that the REMS Patents, including the '976 Patent, the '784 Patent, the '977 Patent, and the '886 Patent, were obtained by fraud because the applicants of these patents concealed from the USPTO prior art that they knew were material to patentability. (*Id.* ¶¶ 282–340). Second, the MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its REMS Patents because the prior art that led the PTAB to invalidate the '720 and '501 Patents would invalidate Celgene's other REMS Patents. (Opp. Br. at 37; MSP SAC ¶¶ 272–79).

e. The Orange Book

The Insurer Plaintiffs' and MSP Plaintiffs' Allegations. The Insurer Plaintiffs and MSP Plaintiffs next allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its '357, '598 and '219 Polymorph Patents because those patents were not listed in the Orange Book by Celgene in association with Revlimid. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). More specifically, they allege that Celgene was required to list with its NDA any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). By asserting patents that were not listed in the Orange Book, the Insurer Plaintiffs and MSP Plaintiffs allege that "Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly, which could give rise to administrative action or potentially additional

antitrust liability if done in an attempt to delay filing and further extend its monopoly." (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434).

The Insurer Plaintiffs raise their sham litigation and orange book allegations under Count II (Violation of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); Count VII (Unjust Enrichment Under State Law); and Count VIII (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Section 2 of the Sherman Act). (Humana Am. Compl. ¶¶ 570–635). The MSP Plaintiffs raise their sham litigation and orange book allegations under Count I (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene and BMS's Violations of Section 2 of the Sherman Act); Count IV (Monopolization and Monopolistic Scheme under State Statutes); Count V (Attempted Monopolization under State Statutes); Count VI (Unfair and Deceptive Trade Practices under State Statutes); and Count VII (Unjust Enrichment Under State Law). (MSP SAC ¶¶ 575–82 & 627–58).

vi. The Co-Pay Assistance Allegations

Fifth, the MSP Plaintiffs also allege that Celgene and BMS made unlawful donations to two co-pay assistance charities, CDF and PAN to fund patient copays of Thalomid and Revlimid. The MSP Plaintiffs are assignees of recovery rights from health plans, including Health Maintenance Organizations ("HMO"); Medicare Advantage Organizations ("MAO"); first-tier, downstream, and related Medicare entities; state Medicaid health care providers; and commercial health plans (collectively, the "Health Plans" or "Assignors"), all of which provide health care coverage and benefits, including prescription drug coverage, to plan beneficiaries. (MSP SAC ¶

14). PAN and CDF are organizations that subsidize drug co-payment obligations of Medicare patients, in part by using donations from pharmaceutical manufacturers. (*Id.* ¶¶ 34 & 36).

The MSP Plaintiffs contend that the Celgene Defendants executed a co-payment circumvention scheme with CDF and PAN that caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs. According to the MSP Plaintiffs, Celgene realized it could overcome doctor and patient cost concerns regarding Thalomid and Revlimid by secretly subsidizing patient co-pay obligations for its drugs through PAN and CDF. (*Id.* ¶ 510). More specifically, the MSP Plaintiffs explain that it is well recognized that an insured's co-pay sharing obligations serves as a market-based check on drug pricing. (*Id.* ¶ 515). By surreptitiously underwriting these cost-sharing obligations, Celgene allegedly "created the illusion for physicians and patients that Revlimid and Thalomid were free (or close to it) when Celgene had merely shifted the entire price burden to third-party payors." (*Id.*). The MSP Plaintiffs allege that, as a result of this scheme, Celgene was able to artificially inflate its prices for Revlimid and Thalomid because it effectively removed the "remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price." (*Id.* ¶ 514). The MSP Plaintiffs further allege that in facilitation of its scheme, Celgene maintained close contact and worked in coordination with the charities to effectuate its goals. (*Id.* ¶ 520). According to the MSP Plaintiffs, Celgene's payments were not made on an ad hoc basis. "Instead, they were based on contractual arrangements under which Celgene agreed to pay designated amounts of money to designated disease funds." (*Id.*). More specifically, the MSP Plaintiffs allege that Celgene received co-pay projections and status reports from PAN and CDF, which included information on the number of applicants that requested co-pay assistance, the average amount of co-pays, total amounts paid out to applicants,

and the amount of Celgene's donations that remained available for use. (*Id.*). Based on that data, Celgene allegedly decided how much to give in "donations" to PAN and CDF to ensure that it would fully fund and offset potential co-pays as needed for the continued sale of its own products, including Thalomid and Revlimid. (*Id.* ¶¶ 520–21). The MSP Plaintiffs allege that by steering people into utilizing CDF and PAN's co-payment assistance funds, the Celgene Defendants and Charity Defendants increased Celgene's number of covered "customers," thereby triggering the Assignors' coverage obligations for those customers and eliminating price sensitivity to Thalomid and Revlimid. (*Id.* ¶ 592). They allege that Celgene, CDF, and PAN provided false certifications asserting that they were complying with federal and state law, including the Anti-Kickback Statute and False Claims Act. (*Id.* ¶ 618). Celgene's payments to PAN and CDF allegedly operated as intended, allowing Celgene to artificially inflate the prices of Revlimid and Thalomid as ultimately covered by the MSP Plaintiffs' Assignors. (*Id.* ¶ 512).

As clarified during oral argument, the MSP Plaintiffs raise their co-pay allegations under all Counts, namely (i) Count I (Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene and BMS's Violations of Sections 2 of the Sherman Act); Count II (Violation of RICO 18 U.S.C. § 1962(c) against Celgene, BMS, CDF and PAN); Count III (Violation of RICO 18 U.S.C. § 1962(d) against Celgene, BMS, CDF and PAN); Count IV (Monopolization and Monopolistic Scheme under State Statutes against Celgene and BMS); Count V (Attempted Monopolization against Celgene and BMS under State Statutes); Count VI (Unfair and Deceptive Trade Practices against Celgene, BMS, CDF and PAN under State Statutes); Count VII (Unjust Enrichment Under State Law against Celgene, BMS, CDF and PAN); and Count VIII (Violations of the Civil Remedies for Criminal Practices Act, Fla. Stat. 77101, *et seq.* against Celgene, BMS, CDF and PAN). (MSP SAC ¶¶ 575–696).

B. Procedural Background

In re Revlimid & Thalomid Purchaser Antitrust Litigation, Civil Action No. 19-7532 represents a set of eleven consolidated antitrust cases. The history of the cases that have been consolidated into this matter is as follows. On March 1, 2019, Humana filed suit against Defendant Celgene for alleged violations of federal and state antitrust laws and consumer protection statutes as well as for unjust enrichment. (D.E. No. 1). Between 2020 and 2022, five other similar actions were either filed in, or transferred to, this District: (i) *United HealthCare Services, Inc. v. Celgene Corporation*, Civil Action No. 20-18531; (ii) *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668;[27] (iii) *Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187; (iv) *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686; and (v) *Molina Healthcare, Inc. v. Celgene Corporation, et al.*, Civil Action No. 22-4561. These six cases were all consolidated on October 17, 2022, under lead docket Civil Action No. 19-7532. (D.E. No. 95). These six consolidated actions will be referred to as the "Insurer Cases" and the Plaintiffs in the Insurer Cases are the previously defined "Insurer Plaintiffs." All of the Insurer Plaintiffs have amended their complaints at least once and have added in Celgene's parent corporation, BMS, as a Defendant. On November 15, 2022, Celgene and BMS filed a consolidated motion to dismiss all of the Insurer Plaintiffs' Operative Complaints. (*See* D.E. No. 104). On June 29, 2023, the Honorable Michael A. Hammer, U.S.M.J, granted one of the Insurer Plaintiffs—United HealthCare Services, Inc. ("UHS")—leave

[27] *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 was initially initiated by three plaintiffs including (i) BCBSM, Inc.; (ii) Health Care Service Corporation; and (iii) Blue Cross and Blue Shield of Florida, Inc. (*Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93)). Plaintiff Health Care Service Corporation stipulated to dismissal of the Amended Complaint's off-label marketing claims asserted in Counts VI through VIII, which only HCSC had asserted. (*Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 102)). As such, those claims are no longer in this suit and are dismissed. Further, on December 1, 2023, Plaintiff BCBSM, Inc. voluntarily dismissed its claims. (D.E. No. 270). As such, the Court addresses the claims of Health Care Service Corporation and Blue Cross and Blue Shield of Florida, Inc. only.

to amend its Complaint. (D.E. No. 198). Though Celgene's consolidated motion to dismiss raises arguments with respect to UHS, those arguments were directed to UHS's original complaint and as such will not be addressed by this Opinion. This Opinion will otherwise address the Celgene Defendants' consolidated motion to dismiss the Operative Complaints of the remainder of the Insurer Plaintiffs.

On November 3, 2022, Plaintiffs Walgreen Co., Kroger Specialty Pharmacy Inc., and CVS Pharmacy, Inc.[28] filed a related action against Celgene and BMS, as well as two additional defendants, Natco Pharma Limited and Teva Pharmaceuticals USA, Inc. (together the "Generic Defendants"). (*See Walgreen Co., et al. v. Celgene Corporation, et al.*, Civil Action No. 22-6440 (the "Walgreen Case")). On November 18, 2022, Plaintiffs Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Jacksonville Police Officers and Fire Fighters Health Insurance Trust; Carpenters and Joiners Welfare Fund; and Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund[29] filed a related action against the Celgene Defendants as well as a number of generic defendants. (*See Jacksonville Police Officers and Fire Fighters Health Insurance Trust, et al. v. Celgene Corp., et al.*, Civil Action No. 22-6694 (the "Jacksonville Case")). On January 24, 2023, the Court also consolidated these two new cases with *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action Number 19-7532. (D.E. No. 122). The Celgene Defendants and the Generic Defendants have filed additional motions to dismiss in the Walgreen Case and Jacksonville Case. (*See* D.E. Nos. 172, 173 & 175). This Opinion will not address the motions to dismiss relevant to the Walgreen Case or Jacksonville Case. At the end of

[28] CVS Pharmacy, Inc was added as a plaintiff in an amended complaint filed on February 16, 2023. (D.E. No. 135).

[29] Carpenters and Joiners Welfare Fund; and Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund were added as plaintiffs in an amended complaint filed on February 16, 2023. (D.E. No. 139). On February 8, 2024, Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund voluntarily dismissed its claims. (D.E. Nos. 321 & 325).

2023, two other similar actions were either filed in, or transferred to, this District: (i) *Intermountain Health Inc. v. Celgene Corporation et al.*, Civil Action Number 23-22117; and (ii) *Mayo Clinic et al. v. Celgene Corporation et al.*, Civil Action number 23-22321. On January 10, 2024, the Court also consolidated these two new cases with *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action Number 19-7532. (D.E. No. 288). On January 22, 2024, Plaintiffs Walgreen Co., Kroger Specialty Pharmacy Inc., and CVS Pharmacy, Inc also filed suit against Dr. Reddy's Laboratories Ltd., and Dr. Reddy's Laboratories, Inc. based upon agreements those entities entered with Celgene. (*Walgreen Co. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action Number 24-0379). On February 9, 2024, the Court also consolidated this case with *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action Number 19-7532. (D.E. No. 324).

Finally, at the end of 2021, the MSP Plaintiffs filed suit against the Celgene Defendants in a case captioned *MSP Recovery Claims, Series LLC., et al. v. Celgene Corporation*, Civil Action No. 21-20451. The MSP Plaintiffs also named as Defendants two co-pay assistance charities, PAN and CDF. Though the MSP Plaintiffs raise many of the same allegations against the Celgene Defendants as the Insurer Plaintiffs, they also raise violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"). (*See generally* MSP SAC). The MSP Case was not consolidated with *In re Revlimid & Thalomid Purchaser Antitrust Litigation*. However, the Celgene Defendants' consolidated motion to dismiss the operative complaints of the Insurer Plaintiffs also seeks to dismiss the MSP Plaintiffs' operative complaint. (*In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action No. 19-7532 (D.E. No. 104); *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 151)). PAN and CDF also filed motions to dismiss the MSP Plaintiffs' operative complaint on November 15,

2022. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 149 & 150)). This Opinion will address the Celgene Defendants' as well as the Charity Defendants' motions to dismiss the MSP Plaintiffs' Second Amended Complaint.

In sum, this Opinion will address the Celgene Defendants' consolidated motion to dismiss the operative complaints in the five following consolidated actions: (i) *Humana, Inc. v. Celgene Corporation*, Civil Action No. 19-7532; (ii) *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668; (iii) *Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187; (iv) *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686; and (v) *Molina Healthcare, Inc. v. Celgene Corporation, et al.*, Civil Action No. 22-4561. It will also address the Celgene Defendants' and Charity Defendants' consolidated motion to dismiss the operative complaint in *MSP Recovery Claims Series LLC et al. v. Celgene Corporation et al.*, No. 21-20451.

Based on the allegations recounted above, the Insurer Plaintiffs bring the following claims:

- **Count I:** Violations of Section 1 of the Sherman Act, 15 U.S.C. § 1
- **Count II:** Violations of Section 2 of the Sherman Act, 15 U.S.C. § 2
- **Count III:** Conspiracy and Combination in Restraint of Trade under State Statutes
- **Count IV:** Monopolization and Monopolistic Scheme under State Statutes
- **Count V:** Attempted Monopolization under State Statutes
- **Count VI:** Unfair and Deceptive Trade Practices under State Statutes
- **Count VII**: Unjust Enrichment Under State Law
- **Count VIII**: Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Sections 1 and 2 of the Sherman Act

(Humana Am. Compl. ¶¶ 570–635).[30] Further the MSP Plaintiffs bring the following claims:

- **Count I:** Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene and BMS's Violations of Section 2 of the Sherman Act
- **Count II:** Violation of Racketeering Influence Corrupt Organization Act ("RICO") 18 U.S.C. § 1962(c) against Celgene, BMS, CDF and PAN
- **Count III:** Violation of RICO 18 U.S.C. § 1962(d) against Celgene, BMS, CDF and PAN
- **Count IV:** Monopolization and Monopolistic Scheme against Celgene and BMS under State Statutes
- **Count V:** Attempted Monopolization against Celgene and BMS under State Statutes
- **Count VI:** Unfair and Deceptive Trade Practices against Celgene, BMS, CDF and PAN under State Statutes
- **Count VII**: Unjust Enrichment Under State Law against Celgene, BMS, CDF and PAN
- **Count VIII**: Violations of the Civil Remedies for Criminal Practices Act, Fla. Stat. 77101, *et seq.* against Celgene, BMS, CDF and PAN

(MSP SAC ¶¶ 575–696). The Celgene Defendants have moved to dismiss the claims made by the Insurer Plaintiffs and MSP Plaintiffs for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). (D.E. No. 104; D.E. No. 104-1 ("Mov. Br.")). In addition, the Celgene Defendants have moved to dismiss the MSP Plaintiffs' RICO and Florida RICO claims for lack of

[30] For purposes of the motions being addressed by the Court, Humana and Cigna are the only Insurer Plaintiffs that are bringing suit as direct purchasers on behalf of certain assignees and thus are asserting federal antitrust claims for damages under the Sherman Act. (*See, e.g.*, Humana Am. Compl. ¶¶ 582–87; *Cigna Corp. v. Celgene Corp.*, 21-11868, (D.E. No. 40 ¶¶ 582–87)). Humana and Cigna bring their Sherman Act claims under Sections 4 (damages) and 16 (injunctive relief) of the Clayton Act, 15 U.S.C. §§ 15 and 26, respectively. The remainder of the Insurer Plaintiffs whose Operative Complaints are being addressed in this Opinion are bringing suit as indirect purchasers and as such are only bringing their Sherman Act claims under Section 16 of the Clayton Act for declaratory and injunctive relief, recognizing the Supreme Court's ruling in *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 747 (1977). *See also McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 856 (3d Cir. 1996) (noting that that the indirect purchaser bar is not an obstacle to injunctive or declaratory relief under Section 16 of the Clayton Act). Health Care is only bringing antitrust claims under state law for (i) Conspiracy and Combination in Restraint of Trade; (ii) Monopolization and Monopolistic Scheme; (iii) Attempted Monopolization; (iv) Unfair and Deceptive Trade Practices; and (v) Unjust Enrichment corresponding to Counts III through VII as listed above. (*Health Care Service Corp. et al. v. Celgene Corp.*, 21-6668) (D.E. No. 93)).

standing. The motion is fully briefed. (D.E. No. 105 ("Opp. Br."); D.E. No. 106 ("Reply")).[31] Likewise the Charity Defendants have moved to dismiss the claims asserted against them by the MSP Plaintiffs under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) and have specifically moved to dismiss the MSP Plaintiffs' RICO and Florida RICO claims for lack of standing. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 149-1 ("PAN Mov. Br."); D.E. No. 150-1 ("CDF Mov. Br.")). Those motions are also fully briefed. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 153 ("Opp. Br. to PAN"); D.E. No. 154 ("Opp. Br. to CDF"); D.E. No. 155 ("PAN Reply"); D.E. No. 157 ("CDF Reply")). The parties also submitted notices of supplemental authority in connection with the motions, which the Court has considered. (*See e.g.*, D.E. Nos. 239, 243, 429 & 436; *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 169, 171, 181–82, 185, 197, 198, 253, 261, 321, 337 & 342)).

The Court held oral argument to address the Celgene Defendants' motions to dismiss on August 18, 2023 and September 18, 2023. (*See* Tr. of Aug. 18, 2023 Oral Arg.; Tr. of Sept. 8, 2023 Oral Arg.). At oral argument, the MSP Plaintiffs clarified to the Court that they are bringing their co-pay allegations against Celgene and BMS under all Counts of their Second Amended Complaint. (Tr. of Sept. 8, 2023 Oral Arg. at 224:8–11). Celgene and BMS indicated to the Court that they were not on notice that these allegations were being brought against them under all Counts. (*Id.* at 225:2–226:20). The Court thereafter requested supplemental briefing from the parties regarding whether the MSP Plaintiffs' Second Amended Complaint placed Celgene and

[31] The Celgene Defendants' consolidated motions to dismiss can be found at Docket Entry Number 104 in Civil Action 19-7532 and Docket Entry Number 151 in Civil Action 21-20451. Because both motions are identical, the Court will refer to the consolidated motion at Docket Entry Number 104, filed in Civil Action Number 19-7532 only. Likewise, the Court will only be referring to the Insurer Plaintiffs and MSP Plaintiffs' consolidated opposition at Docket Entry Number 105 and the Celgene Defendants' consolidated reply at Docket Entry Number 106 in Civil Action Number 19-7532.

BMS on sufficient notice that the co-pay allegations were being asserted under all Counts of the Second Amended Complaint. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 235)). The parties have since submitted supplemental briefing on that issue. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 240 ("Celgene. Supp. Br."); D.E. No. 244 ("MSP Supp. Opp.") & D.E. No. 246 ("Celgene Supp. Reply")). The Court is now prepared to rule.

II. LEGAL STANDARD

A. Rule 12(b)(1)

Under Rule 12(b)(1), a court may dismiss a claim at the pleading stage if the court does not have jurisdiction. "A motion to dismiss for want of standing is also properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). Plaintiffs have the burden of establishing their standing in federal court. *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 278 (3d Cir. 2014) (citing *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005)). "Two types of challenges can be made under Rule 12(b)(1)—'either a facial or a factual attack.'" *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 632 (3d Cir. 2017) (quoting *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016)). In assessing a facial challenge, the Court accepts the factual allegations as true. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).[32]

B. Rule 12(b)(6)

In assessing whether a complaint states a cause of action sufficient to survive dismissal under Rule 12(b)(6), the Court accepts "all well-pleaded allegations as true and draw[s] all

[32] Here, PAN and CDF facially attack the MSP Plaintiffs' standing. (*See* PAN Mov. Br. at 14 & 16–19; CDF Mov. Br. at 37–39).

reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id*. at 878–79 (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012)). The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and a claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (first quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010); and then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

III. DISCUSSION

A. The MSP Plaintiffs' Standing

The Charity Defendants contend that the claims asserted against them by the MSP Plaintiffs must be dismissed because the MSP Plaintiffs lack Article III standing. (PAN Mov. Br. at 14 & 16–19; CDF Mov. Br. at 37–39). Specifically, the Charity Defendants contend that the MSP Plaintiffs have failed to allege an injury-in-fact suffered by the MSP Plaintiffs' named Assignors that is traceable to the Charity Defendant's conduct. (PAN Mov. Br. at 16–17; CDF Mov. Br. at 37–39). Further, PAN contends that the assignments by the MSP Plaintiffs' Assignors do not give the MSP Plaintiffs standing to bring claims in this case. (PAN Mov. Br. at 17–19). The Court addresses the Charity Defendants' arguments in turn.

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" *Lance v. Coffman*, 549 U.S. 437, 439 (2007). "Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "The standing inquiry . . . focuse[s] on whether the party invoking jurisdiction

had the requisite stake in the outcome when the suit was filed." *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 360 (3d Cir. 2014) (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)). To establish Article III standing, "[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo*, 578 U.S. at 338. "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." *Id.* (citing *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990)). During the pleading stage, "general factual allegations" showing these elements suffice. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). And "the assignee of a claim has standing to assert the injury-in-fact suffered by the assignor." *Sprint Commc'ns Co., L.P. v. APCC Servs., Inc.*, 554 U.S. 269, 286 (2008).

i. Assignments

To start, as noted, PAN contends that the assignments by the MSP Plaintiffs' Assignors do not give the MSP Plaintiffs standing to bring claims in this case. (PAN Mov. Br. at 17–19). As an initial matter, as PAN points out (PAN Reply at 3), the MSP Plaintiffs cannot sue on behalf of unnamed Assignors because their Second Amended Complaint pleads no facts establishing that those assignors would have standing to sue on their own. *See, e.g.*, *MSP Recovery Claims, LLC v. Actelion Pharm. US, Inc.*, No. 22-7604, 2023 WL 5725517, at *8 (N.D. Cal. Sept. 5, 2023). Rather, "to establish standing, the plaintiffs must name or otherwise identify every entity whose claims they assert." *MSP Recovery Claims, Series LLC v. Pfizer, Inc.*, No. 22-1419, 2024 WL 1344446, at *4 (D.D.C. Mar. 30, 2024) (internal quotations and citation omitted). Nevertheless, as will be discussed below, the MSP Plaintiffs have adequately alleged standing to sue on behalf of their Named Assignors. (MSP SAC at 170–76).

The MSP Plaintiffs allege that their Assignors are Health Maintenance Organizations; Medicare Advantage Organizations; first-tier, downstream, and related Medicare entities; state Medicaid health care providers; and commercial health plans, all of which provide health care coverage and benefits, including prescription drug coverage, to plan beneficiaries. (MSP SAC ¶ 14). The MSP Plaintiffs describe assignments from six named entities in their Second Amended Complaint. (*Id.* at 170–76). PAN contends that each of these assignments is insufficient to give the MSP Plaintiffs standing. The Court examines each of PAN's arguments in turn.

The Third Circuit has held that the assignment of any claims must be "express" in order to be deemed valid. *Lerman v. Joyce Int'l, Inc.*, 10 F.3d 106, 112 (3d Cir. 1993). An "express" assignment must make reference to "legal causes of action or claims" in a manner that is "unambiguous and all-inclusive." *Id.* In contrast, "general assignment[s]" of "rights, title and interest" are not sufficiently express to adequately assign legal claims. *Lerman*, 10 F.3d at 112; *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 438 (3d Cir. 1993).

First, PAN contends that three assignments made by Interamerican Medical Group Center, LLC ("IMC"), Pura Vida Medical Center, LLC ("Pura Vida"), and Sal Health Group, LLC ("Sal Health"), are insufficient to give the MSP Plaintiffs standing to sue because those entities are not included in the government's public list of Medicare Advantage Organizations and appear not to be health insurance companies. (PAN Mov. Br. at 17). As such, PAN contends that none of these Assignors could have possessed the causes of action asserted in the MSP Plaintiffs' Second Amended Complaint. (*Id.*). In Opposition, the MSP Plaintiffs contend that the assignments from IMC, Pura Vida, and Sal Health give them standing to sue because those assignors are "first-tier and/or downstream entities that contracted with MAOs to provide certain services for Medicare beneficiaries." (Opp. Br. to PAN at 16). The Court finds that at this stage the assignments from

IMC, Pura Vida, and Sal Health are sufficient to give the MSP Plaintiffs standing to sue. Here, the MSP Plaintiffs expressly allege that their Assignors are Health Maintenance Organizations; Medicare Advantage Organizations; first-tier, downstream, and related Medicare entities; state Medicaid health care providers; and commercial health plans, "all of which provide health care coverage and benefits, including prescription drug coverage, to plan beneficiaries." (MSP SAC ¶ 14; *see also id.* ¶ 556). Whether IMC, Pura Vida, and Sal Health actually provide such coverage and benefits, and to what extent, is a question of fact that this Court cannot adjudicate at this stage on the current record. *See Sanofi*, 2019 WL 1418129, at *10 (rejecting the defendants' argument that IMC could not have suffered an injury from allegedly inflated prices of drugs as a medical services provider and health clinic because the complaint alleged that IMC provided Medicare benefits and the extent to which it provided Medicare benefits raised a question of fact the court could not address on a motion to dismiss); *Pfizer*, 2024 WL 1344446, at *6.

Second, PAN contends that although the MSP Plaintiffs allege that they were assigned claims from Health First Health Plans, Inc., multiple courts have reviewed the assignment in question and have held that it did not assign claims of Health First Health Plans, Inc., but rather those of a separate company, and have therefore dismissed the MSP Plaintiffs' claims for lack of standing. (PAN Mov. Br. at 17 (citing *MSP Recovery Claims, Series LLC v. QBE Holdings, Inc.*, 965 F.3d 1210 (11th Cir. 2021) and *MAO-MSO Recovery II, LLC v. State Farm Mut. Automobile Ins. Co.*, No. 17-1541, 2018 WL 2392827 (C.D. Ill. June 7, 2018))). As such, PAN contends that the MSP Plaintiffs are collaterally estopped from asserting the claims of Health First Health Plans, Inc. (*Id.* at 18). In Opposition, the MSP Plaintiffs contend that the courts in *QBE Holdings* and *State Farm* found that they lacked standing after considering different contractual documents than those at issue in this case and as such should not be collaterally estopped from asserting the claims

of Health First Health Plans, Inc. in this case. (Opp. Br. to PAN at 18–20). The Court finds that at this stage the assignment from Health First Health Plans, Inc. is sufficient to give the MSP Plaintiffs standing to sue.

In both *QBE Holdings* and *State Farm*, the courts addressed whether an assignment gave the MSP Plaintiffs standing to sue under the Medicare Secondary Payer Act. In those cases, the MSP Plaintiffs sought to bring suit on behalf of Medicare Advantage Organizations seeking to recover unreimbursed payments. *QBE Holdings, Inc.*, 965 F.3d at 1215; *State Farm*, 2018 WL 2392827, at *4. Both courts noted that the assignments in question assigned claims from an entity known as Health First Administrative Plans, which provided administrative functions for Health First Health Plans, Inc. *QBE Holdings, Inc.*, 965 F.3d at 1215; *State Farm*, 2018 WL 2392827, at *4–5. Specifically, the courts in those cases considered an assignment dated April 28, 2016 that assigned to MSP Recovery all rights to recover conditional payments on behalf of Health First Administrative Plans, as well as a subsequent assignment dated in 2017 that assigned all claims from MSP Recovery to a designated series of MSP Recovery Claims Series, LLC, Series 16-05-456. *QBE Holdings, Inc.*, 965 F.3d at 1215–16; *State Farm*, 2018 WL 2392827, at *3–5. Health First Administrative Plans, however, was not an MAO and did not pay the medical expenses at issue in those cases. *QBE Holdings, Inc.*, 965 F.3d at 1215–16; *State Farm*, 2018 WL 2392827, at *4–6. Rather, it only provided administrative functions for Health First Health Plans, Inc., an entity that was an MAO and did make the unreimbursed payments. *QBE Holdings, Inc.*, 965 F.3d at 1215–16; *State Farm*, 2018 WL 2392827, at *4–6. Recognizing that the assignments in question did not assign the rights of Health First Health Plans, Inc., but rather assigned the rights of Health First Administrative Plans—which had no rights under the Medicare Secondary Payer Act—the

courts in *QBE Holdings* and *State Farm* held that the assignments did not give the MSP Plaintiffs standing. *QBE Holdings, Inc.*, 965 F.3d at 1215–22; *State Farm*, 2018 WL 2392827, at *5.

Here, the MSP Plaintiffs allege that on April 28, 2016, Health First Health Plans, Inc.—not Health First Administrative Plans—irrevocably assigned to MSP Recovery all rights "to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees." (MSP SAC at 173–74). They then allege that on June 12, 2017, MSP Recovery assigned all rights it acquired from Health First Health Plans, Inc. to Series 16-05-456. (*Id.* at 174 ([T]he undersigned Assignor . . . irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the Claims and Assigned Claims . . . as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization . . . and [MSP Recovery]")). The MSP Plaintiffs then allege that on October 22, 2020, Series, 16-05-456 assigned these claims to Series 44-20-456. (*Id.* at 174–75). There is nothing on the face of the MSP Plaintiffs' Second Amended Complaint to indicate that these specific assignments actually assigned claims from Health First Administrative Plans, rather than from Health First Health Plans Inc. Though the MSP Plaintiffs contend that the courts in *QBE Holdings* and *State Farm* considered different contractual documents than those at issue in this case, including the 2017 Assignment to Series 16-05-456, PAN provides no argument to contest this interpretation. (Opp. Br. to PAN at 18–20; *see generally* PAN Reply). Whether the specific assignments in question actually assigned the claims of Health First Health Plans Inc. raises a question of fact that this Court cannot adjudicate based on the present record. *See Sanofi*, 2019 WL 1418129, at *10.

As such, the Court finds that at this stage the assignment from Health First Health Plans, Inc. is sufficient to give the MSP Plaintiffs standing to sue and that the MSP Plaintiffs are not collaterally estopped from asserting the claims of Health First Health Plans, Inc. *See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (noting that collateral estoppel is appropriate when the identical issue was previously adjudicated); *see also MSP Recovery Claims, Series LLC v. United Servs. Auto. Ass'n*, No. 20-21530, 2022 WL 1555081, at *2 n.1, 6 (S.D. Fla. May 17, 2022) (finding that the MSP Plaintiffs sufficiently alleged standing based on assignments made from Health First Health Plans, Inc., which assigned its rights to MSP Recovery, LLC on April 28, 2016 and from MSP Recovery, LLC which then assigned the Health First Health Plans, Inc. rights to Series 16-05-456 on June 12, 2017).

Third, PAN contends that though the Second Amended Complaint indicates that Assignors SummaCare, Inc. ("SummaCare") and Preferred Medical Plan, Inc. ("Preferred") assigned certain claims to the MSP Plaintiffs, the assignments as alleged do not indicate how the assigned "claims" are defined. (PAN Mov. Br. at 18). Because assignments of claims must be express, PAN contends that the Second Amended Complaint does "not adequately allege that these two Assignors assigned the claims pled in this case." (*Id.*). In Opposition, the MSP Plaintiffs contend that the assignments from SummaCare and Preferred adequately assigned the claims pled in this case, as those assignments include language assigning all state and federal claims. (Opp. Br. to PAN. at 20–21). The Court agrees with the MSP Plaintiffs. Here, both the SummaCare and Preferred assignments as alleged expressly set forth the respective Assignors' intention that the MSP Plaintiffs be assigned any and all rights of recovery, including from the alleged co-pay circumvention scheme. More specifically, the SummaCare assignment contract, which took effect on May 12, 2017, assigns broad legal rights, stating in pertinent part:

> [SummaCare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [SummaCare]'s right, title, ownership and interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [SummaCare] that [SummaCare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [SummaCare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]"

(MSP SAC at 170). Similarly, the Preferred assignment contract, which took effect on May 3, 2016, also assigns broad legal rights, stating in pertinent part:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recovery monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assignees Claims"

(MSP SAC at 172). As another court in this district has recognized in analyzing nearly identical language in assignments made to some of the MSP Plaintiffs, the agreements between the relevant MSP Plaintiffs and SummaCare and Preferred "are sufficiently express and, when reading the contract 'as a whole, and with common sense' it is clear that the [MSP] Plaintiffs' Assignors intended that [MSP] Plaintiffs bring any and all viable claims," including those the MSP Plaintiffs are asserting in this case. *Sanofi*, 2019 WL 1418129, at *8 (citing *A.D.L. v. Cinnaminson Twp. Bd. of Educ.*, 975 F. Supp. 2d 459, 466 (D.N.J. 2013)). In fact, both agreements note that the relevant MSP Plaintiffs' "rights to recover thereunder are not limited to any particular statute but

are all-encompassing with respect to payments made by the assignors." *Id.* As such, the SummaCare and Preferred assignments encompass the claims asserted in the MSP Plaintiffs' Second Amended Complaint.

Fourth, PAN contends that the assignments from SummaCare, Preferred, and Health First Health Plans, Inc. do not cover any *timely* RICO claims. (PAN Mov. Br. at 18). More specifically, PAN notes that the assignments from SummaCare, Preferred, and Health First Health Plans, Inc. are dated May 12, 2017, May 3, 2016, and April 28, 2016, respectively, and cover only claims "existing on the date [there]of." (*Id.* at 19). However, PAN asserts that any RICO claims existing as of those dates are time barred under RICO's four-year statute of limitations. (*Id.*; *see also* PAN Reply at 1–2). In Opposition, the MSP Plaintiffs contend that their RICO claims are not time-barred because their RICO claims did not accrue until October 25, 2019, at the earliest and the execution of the disputed assignment agreements did not trigger the accrual of any causes of action. (Opp. Br. to PAN at 22–25). Regardless, the MSP Plaintiffs contend that the class action tolling doctrine, doctrine of fraudulent concealment, and continuing violation doctrine indicate that their RICO claims are not time barred. (*Id.* at 23 n.41).

The Court will not dismiss the MSP Plaintiffs' Second Amended Complaint for lack of standing based on PAN's statute of limitations argument. While standing is a jurisdictional matter than can be raised through a Rule 12(b)(1) motion, a motion to dismiss on statute of limitations grounds generally is treated as a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6), as opposed to under Rule 12(b)(1). Rule 12(b)(6) provides the most appropriate legal basis for a motion to dismiss on such grounds because expiration of the statute of limitations presents an affirmative defense that is generally raised in the defendant's answer. *Compare* Fed. R. Civ. P. 12(b)(1) (allowing a party to assert lack of

subject-matter jurisdiction by motion), *with* Fed. R. Civ. P. 8(c) (stating that a party must state a statute-of-limitations defense in his responsive pleading), *and Robinson v. Johnson*, 313 F.3d 128, 134–35 (3d Cir. 2002). Thus, to the extent PAN attempts to use Rule 12(b)(1) to preemptively raise a statute-of-limitations defense, the Court rejects this approach, and will not dismiss the MSP Plaintiffs' Second Amended Complaint for lack of standing based on PAN's statute of limitations argument.[33] *Diamond v. Pennsylvania State Educ. Ass'n*, 399 F. Supp. 3d 361, 404 (W.D. Pa. 2019), *aff'd,* 972 F.3d 262 (3d Cir. 2020); *Pfizer*, 2024 WL 1344446, at *6. As such, the Court finds that the assignments by the MSP Plaintiffs' named Assignors give the MSP Plaintiffs standing to bring claims in this case.

ii. Injury-in-fact and Traceability

Next, the Charity Defendants contend that the MSP Plaintiffs have failed to allege an injury-in-fact suffered by the MSP Plaintiffs' Assignors that is traceable to the Charity Defendants' conduct. (PAN Mov. Br. at 16–17; CDF Mov. Br. at 37–39). More specifically, the Charity Defendants contend that the MSP Plaintiffs' Second Amended Complaint contains no allegations establishing that any of the MSP Plaintiffs' Assignors are health insurers that provided reimbursement for purchases of Revlimid or Thalomid or that the patients whose claims they reimbursed received co-pay assistance from PAN or CDF. (PAN Mov. Br. at 16–17; CDF Mov. Br. at 37–39). In Opposition, the MSP Plaintiffs contend that they have sufficiently pled the existence of a scheme between the Celgene Defendants and Charity Defendants that caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs. (Opp. Br. to PAN at 14–16; Opp. Br. to

[33] Because, as will be discussed below, the Court dismisses the MSP Plaintiffs' RICO claims for lack of statutory standing, it does not reach PAN's statute of limitations arguments.

CDF at 38–40). As such, the MSP Plaintiffs contend that they have sufficiently alleged their Assignors' injuries—paying claims for overpriced drugs—traceable to the illicit scheme. The Court agrees with the MSP Plaintiffs.

Recognizing that Article III only requires "general factual allegations" of the standing elements, *Lujan*, 504 U.S. at 561, it is plausible to infer that the MSP Plaintiffs' named Assignors suffered an economic injury that is fairly traceable to the Charity Defendants' conduct. Here, the MSP Plaintiffs' Second Amended Complaint pleads the existence of a scheme between the Celgene Defendants and Charity Defendants that caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs. (MSP SAC ¶¶ 502–552 & 558). More specifically, they allege that Celgene realized it could overcome doctor and patient cost concerns regarding Thalomid and Revlimid and drive up prescription volume by secretly subsidizing patient co-pay obligations for its drugs through PAN and CDF. (*Id.* ¶ 510). "By surreptitiously underwriting these cost-sharing obligations, Celgene [allegedly] created the illusion for physicians and patients that Revlimid and Thalomid were 'free' (or close to it) when Celgene had merely shifted the entire price burden to third-party payors . . . ." (*Id.* ¶ 515). The MSP Plaintiffs further allege that, in facilitation of its scheme, "Celgene maintained close contact and worked in coordination with the Charity Defendants to effectuate its goals." (*Id.* ¶ 520). They allege that Celgene received co-pay projections from PAN and CDF, which included information on the number of applicants that requested co-pay assistance, the average amount of co-pays, total amounts paid out to applicants, and the amount of Celgene's donations that remained available for use. (*Id.*) Based on that data, Celgene allegedly decided how much to give in donations to PAN and CDF to ensure that it would offset potential co-pays as needed for the continued sale of its own products. (*Id.* ¶¶ 520–21). The

MSP Plaintiffs allege that, as a result of this scheme, Celgene was able to artificially inflate its prices for Revlimid and Thalomid because it effectively removed the "remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price." (*Id.* ¶ 514). For example, they allege that by "2019, the price of a single dose of Revlimid cost $719.82—nearly a 300% increase over the cost of the drug from 2007." (*Id.* ¶ 545). As discussed above, the MSP Plaintiffs allege that their Assignors are Health Maintenance Organizations; Medicare Advantage Organizations; first-tier, downstream, and related Medicare entities; state Medicaid health care providers; and commercial health plans, all of which provide health care coverage and benefits, including prescription drug coverage, to plan beneficiaries. (*Id.* ¶ 14). And as discussed, in the Second Amended Complaint, the MSP Plaintiffs describe assignments from six named entities. (*Id.* at 170–76). Further, the MSP Plaintiffs allege that their Assignors' claims data confirms that those Assignors "purchased and/or reimbursed the cost for Thalomid and Revlimid." (*Id.* ¶ 32). In fact, they allege that their Assignors paid substantial sums to purchase Thalomid and Revlimid from 2007 to the present, totaling to about $251,449,930.22. (*Id.* ¶¶ 496–99). They further allege that the prices their Assignors paid for Revlimid and Thalomid were inflated in part as a result of the co-pay circumvention scheme orchestrated by the Celgene Defendants and Charity Defendants. (*Id.* ¶¶ 558 & 593). Based on these allegations, the Court finds that it is plausible to infer that the MSP Plaintiffs' named Assignors suffered an economic injury from the increase in Revlimid and Thalomid prices and that the price increases are fairly traceable to the Celgene Defendants' and Charity Defendants' co-pay circumvention scheme.

CDF contends that to demonstrate standing the MSP Plaintiffs must set forth factual allegations showing: (i) the existence of an enrollee who filled a prescription for Revlimid or Thalomid; (ii) the amount, if any, paid by the Assignor for that prescription and when payment

was made; (iii) the Enrollee's co-pay obligation, if any, for the prescription; (iv) whether CDF paid any portion of the copay with funds donated by Celgene; and (v) a causal link between the foregoing and any harm inflicted upon the Assignor (namely, that the prescription otherwise would not have been made or filled). (CDF Mov. Br. at 38–39).[34] The Court is not convinced that such detailed allegations are necessary at this stage. There is no applicable heightened pleading requirement that requires greater specificity to allege standing, as the Charity Defendants suggest, beyond what the MSP Plaintiffs have already alleged. Though the MSP Plaintiffs' Second Amended Complaint lacks evidence that shows precisely when the MSP Plaintiffs' named Assignors provided reimbursement for Revlimid and Thalomid and in what amount, or whether the patients whose claims the MSP Plaintiffs' named Assignors reimbursed received co-pay assistance from PAN or CDF with donations made by Celgene, the Court is not convinced that the MSP Plaintiffs must include specific documents or bills of this type at this stage in the proceeding, given that "general factual allegations" suffice to establish standing. *Lujan*, 504 U.S. at 561. Further, the Second Amended Complaint alleges that the MSP Plaintiffs' Assignors "purchased and/or reimbursed the cost for Thalomid and Revlimid." (MSP SAC ¶ 32). And it further alleges that by steering people into utilizing CDF and PAN's co-payment assistance funds, the Celgene Defendants and Charity Defendants increased Celgene's number of covered "customers," thereby triggering the Assignors' coverage obligations for their enrollees and causing the Assignors to pay "increased claims for prescriptions where CDF or PAN[] made the copayment." (*Id.* ¶¶ 592 & 607). Such allegations allow the Court to draw the inference that the MSP Plaintiffs' named Assignors provided reimbursement for purchases of Revlimid or Thalomid and that the patients whose claims the MSP Plaintiffs' named Assignors reimbursed received co-pay assistance from

[34] While CDF also contends that the MSP Plaintiffs must allege that they have the legal right to seek recovery for their Assignors' injuries (CDF Mov. Br. at 39), it does not contest the validity of any assignments. (*See id.*)

PAN or CDF. As such, the Court finds that at this stage, it is plausible to infer that the MSP Plaintiffs' named Assignors suffered an economic injury from the increase in Revlimid and Thalomid prices and that the price increases are fairly traceable to the Celgene Defendants' and Charity Defendants' co-pay circumvention scheme. *See, e.g.*, *MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 18-2211, 2019 WL 1418129, at *10 (D.N.J. Mar. 29, 2019) (finding that the plaintiffs adequately alleged injury-in-fact where they pled the existence of a scheme to inflate insulin prices coupled with allegations of purchases made by plaintiffs' assignors); *MSP Recovery Claims, Series LLC v. Lundbeck LLC*, 664 F. Supp. 3d 635, 650 (E.D. Va. 2023) (finding that the plaintiffs adequately alleged that their assignors suffered an economic injury from a co-pay scheme that eliminated price sensitivity and led to an increase in drug prices, and that the price increase was fairly traceable to the defendants' conduct even though plaintiffs did not include documentation showing which patients received co-payment assistance, when the assignors reimbursed claims for the drug, and at what price). In sum, the Court finds that the MSP Plaintiffs have adequately alleged an injury-in-fact traceable to the Charity Defendants' conduct and that the assignments made by their named Assignors give them standing to sue.

B. The MSP Plaintiffs' RICO Claims

The Court will now analyze the sufficiency of the MSP Plaintiffs' RICO claims asserted against Celgene, BMS, PAN, and CDF. Relevant here, the MSP Plaintiffs' Second Amended Complaint alleges that the Celgene Defendants and Charity Defendants (i) violated the RICO Act pursuant to 18 U.S.C. § 1962(c) and (ii) conspired to violate the RICO Act pursuant to 18 U.S.C. § 1962(d). (MSP SAC ¶¶ 583–626). To support their substantive RICO claim and the RICO conspiracy claim, the MSP Plaintiffs allege that the Celgene Defendants engaged in a scheme with

CDF and PAN that caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs.

The RICO statute makes it "unlawful for any person employed by or associated with any enterprise . . . to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c). To plead a RICO claim under section 1962(c), "the plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 362 (3d Cir. 2010) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004)). "[A]n 'enterprise' includes 'any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.'" *Id.* at 362–63 (quoting 18 U.S.C. § 1961(4)). "'Racketeering activity' means one of the various predicate acts identified in [18 U.S.C. § 1961(1)], including acts 'indictable' under the federal mail and wire fraud statutes." *Bonavitacola Elec. Contractor, Inc. v. Boro Developers, Inc.*, 87 Fed. App'x 227, 231 (3d Cir. 2003) (citing 18 U.S.C. § 1961(1)). A "pattern of racketeering activity" requires at least two predicate acts of racketeering within a ten-year period. *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 363. The predicate acts can include federal mail fraud or federal wire fraud. *Id.*

The RICO statute also makes it unlawful for any person to conspire to violate the RICO statute. 18 U.S.C. § 1962(d). The essential elements of a section 1962(d) conspiracy claim include: (i) knowledge of the corrupt enterprise's activities and (ii) agreement to facilitate those activities. *Salinas v. U.S.*, 522 U.S. 52, 66 (1997). There is no requirement of an overt act and, thus, "a defendant may be held liable for conspiracy to violate section 1962(c) if he knowingly agrees to facilitate a scheme which includes the operation or management of a RICO enterprise." *Smith v. Berg*, 247 F.3d 532, 538 (3d Cir. 2001).

The Celgene Defendants and Charity Defendants seek to dismiss both the substantive RICO claim and the RICO conspiracy claim, contending that the MSP Plaintiffs lack statutory standing because the MSP Plaintiffs' Assignors did not purchase Thalomid or Revlimid directly from Celgene. According to the Celgene Defendants and Charity Defendants, the MSP Plaintiffs' Assignors are "end-payers" or "indirect purchasers" in the distribution chain who pay for drugs purchased by a pharmacy, wholesaler, or their insured. (Mov. Br. at 53–54; PAN Mov. Br. at 23–25; CDF Mov. Br. at 9–11). Citing the "indirect purchaser" rule set forth by the United States Supreme Court in *Illinois Brick Co. v. Illinois*, the Celgene Defendants and Charity Defendants assert that the MSP Plaintiffs are barred from bringing RICO claims. (Mov. Br. at 53–54; PAN Mov. Br. at 23–25; CDF Mov. Br. at 9–11). For the reasons set forth below, the Court agrees with the Celgene Defendants and Charity Defendants and finds that the MSP Plaintiffs are barred from bringing RICO claims pursuant to the indirect purchaser rule.

The United States Supreme Court originally developed the indirect purchaser rule in the antitrust context, holding that Clayton Act[35] plaintiffs could not demonstrate injury by providing evidence of indirect purchases. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 737 (1977). Central to the Supreme Court's holding was the notion that allowing indirect purchasers to recover would "transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant." *Id.* at 740. "This 'indirect purchaser rule' was intended to prevent defendants from being exposed to the 'multiple liability' that would occur if both indirect and direct purchasers in the distribution chain could assert claims arising out of a single overcharge. *Humana, Inc. v. Indivior Inc.*, No. 20-4602,

[35] The Clayton Act creates a private cause of action for damages suffered as a result of a defendant's violation of the antitrust laws. *See McCarthy*, 80 F.3d at 856 n.20 (citing 15 U.S.C. § 15(a)).

2021 WL 3101593, at *8 (E.D. Pa. July 22, 2021), *aff'd,* No. 21-2573, 2022 WL 17718342 (3d Cir. Dec. 15, 2022) (citing *McCarthy*, 80 F.3d at 851).

Following *Illinois Brick*, the Third Circuit in *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 851 (3d Cir. 1996) addressed whether indirect purchasers had standing to bring RICO claims. In *McCarthy*, a group of plaintiffs who were indirect purchasers brought antitrust and RICO claims against the defendant sellers. *Id.* at 845. Emphasizing that "all of the policy concerns expressed in *Illinois Brick* [we]re implicated" in *McCarthy*, the Third Circuit held that the "indirect purchaser" rule of *Illinois Brick* applied "equally to allegations of RICO violations" and, as such, found that indirect purchasers lack standing to pursue claims under RICO. *Id.* at 851, 855. Because the plaintiffs in *McCarthy* could not establish that they were direct purchasers, the Third Circuit concluded that the plaintiffs lacked standing to assert their RICO claims. *Id.* at 855.

The Third Circuit most recently reiterated *McCarthy*'s holding in a non-precedential decision in *Humana, Inc. v. Indivior, Inc.*, No. 21-2573, 2022 WL 17718342 (3d Cir. Dec. 15, 2022). In *Humana*, the plaintiffs, health benefit program insurers, brought substantive RICO and conspiracy RICO claims against the defendants, alleging that the defendants fraudulently induced them to include a prescription drug, Suboxone film, on an approved list of medications covered by their members' health insurance plans. *Humana*, 2022 WL 17718342, at *1. The district court dismissed the plaintiffs' complaints, reasoning that, "because [the plaintiffs] merely reimbursed the purchase of Suboxone film, they were indirect purchasers of the drug and therefore lacked standing under the indirect-purchaser rule, first articulated in [*Illinois Brick*], and subsequently applied by the [Third Circuit] to RICO cases in [*McCarthy*]." *Id.* The Third Circuit affirmed the decision of the district court, holding that insurers that merely reimbursed prescriptions for a drug were indirect purchasers and therefore lacked RICO standing under the indirect purchaser rule.

Humana, 2022 WL 17718342, at *2–3. The Third Circuit rejected RICO standing under the indirect purchaser rule because, as in antitrust cases, "pecuniary recoveries by indirect purchasers would 'transform treble-damage actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant.'" *Id.* at *3 (quoting *Illinois Brick*, 431 U.S. at 737).

McCarthy's bar on indirect purchaser standing in the RICO context has also been cited with approval by district courts in the Third Circuit on multiple recent occasions. *See e.g.*, *Hu v. BMW of N. Am. LLC*, No. 18-4363, 2021 WL 1138123, at *2 (D.N.J. Mar. 24, 2021) ("Though *McCarthy* was decided twenty-five years ago, courts in this district continue to apply it to dismiss RICO claims." (citing cases)); *Minnesota by Ellison v. Sanofi-Aventis U.S. LLC*, No. 18-14999, 2020 WL 2394155, at *9 (D.N.J. Mar. 31, 2020) ("[O]nly the purchaser immediately downstream from the alleged [RICO violator] possesses standing to pursue an action." (alteration in original) (internal quotation marks omitted)); *In re Insulin Pricing Litig.*, No. 17-0699, 2019 WL 643709, at *8, *12 (D.N.J. Feb. 15, 2019) (reiterating *McCarthy*'s holding that "antitrust standing principles apply equally to allegations of RICO violations" and, thus, indirect purchasers were precluded from pursuing RICO violations, even when improper price inflation is passed along on a "dollar for dollar" basis (internal quotation marks and citations omitted)); *MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 18-2211, 2019 WL 1418129, at *16 (D.N.J. Mar. 29, 2019) (finding, under *McCarthy*, that heightened coinsurance payments for insulin did not give RICO standing to plaintiff end payors because they failed to allege that they directly purchased insulin from defendants); *MSP Recovery Claims, Series LLC v. Abbott Lab'ys*, No. 19-21607, 2021 WL 2177548, at *7–8 (D.N.J. May 28, 2021) (finding, under *McCarthy*, the plaintiffs lacked RICO standing because they failed to allege that they directly purchased defendants' test strip products);

Indivior Inc., 2021 WL 3101593, at *8–12 (finding based on *McCarthy* that insurers that merely reimbursed prescriptions for a drug were indirect purchasers and therefore lacked RICO standing under the indirect purchaser rule).

Based on this clear Third Circuit precedent, the Court finds that the MSP Plaintiffs lack standing to pursue their RICO claims. The MSP Plaintiffs contend that the Celgene Defendants engaged in a scheme with CDF and PAN that caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs. (*See* MSP SAC ¶¶ 502–52). However, the MSP Plaintiffs do not allege that they or their Assignors purchased Thalomid or Revlimid directly from Celgene, nor can they. Rather, the MSP Plaintiffs expressly allege that their Assignors are "third party payers" and "end-payers" of Thalomid or Revlimid at the end of a "chain of distribution" behind "wholesale distributors, specialty distributors, [and] pharmacies." (MSP SAC ¶ 32 ("As *third-party payers* of pharmaceutical claims for their Enrollees, Assignors are '*end-payers*' for their Enrollees' Thalomid and Revlimid prescriptions and are thereby injured as a result of Celgene's unlawful behavior." (emphasis added)); *id.* ¶ 504 ("The only entities harmed in these types of schemes are *third party payers* such as Assignors and the Class Members. This is principally because there are no violations of law among the chain of distribution until the unlawful co-payment is provided through the conduit (from Celgene) and a bill is submitted to the *third-party payer*. Additionally, wholesale distributors, specialty distributors, and/or pharmacies actually benefit from the scheme as their sales increase because the rate of abandonment decreases" (emphasis added))). In other words, the MSP Plaintiffs do not allege that their Assignors directly purchased Thalomid and Revlimid from Celgene, but rather that their Assignors reimbursed prescriptions for Thalomid and Revlimid that were already purchased by a pharmacy, wholesaler, or their insured. (*Id.* ¶ 504; *id.*

¶¶ 690–91 ("As part of this scheme, Celgene and CDF" or PAN "caused pharmacies to submit false certifications and misled Assignors and the Class Members into *reimbursing prescriptions of Thalomid and Revlimid*." (emphasis added))). Further, the MSP Plaintiffs at no point dispute that their Assignors were indirect purchasers of Revlimid and Thalomid. (*See generally* Opp. Br.; Opp. Br. to PAN; Opp. Br. to CDF). As such, the MSP Plaintiffs' Assignors are multiple purchasers down the distribution chain from Celgene and are quintessential indirect purchasers for the purposes of the indirect purchaser rule. As a result, the MSP Plaintiffs lack standing to pursue their alleged RICO claims. *See McCarthy*, 80 F.3d at 848, 855 (holding that "only the purchaser immediately downstream from the alleged [RICO violator]" possesses standing to pursue an action); *Indivior*, 2021 WL 3101593, at *12 (dismissing substantive RICO claim under 18 U.S.C. § 1962(c) and the RICO conspiracy claim under 18 U.S.C. § 1962(d) pursuant to the indirect purchaser rule); *see also Abbott Labs.*, 2021 WL 2177548, at *9 n.12.

The MSP Plaintiffs' arguments to the contrary are unavailing. *First*, the MSP Plaintiffs contend that the Supreme Court has rejected applying the indirect purchaser rule to RICO claims. (Opp. Br. at 52–53; Opp. Br. to CDF at 1–3). To support this argument, the MSP Plaintiffs cite to the Supreme Court's decision in *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258 (1992), which they contend held that RICO statutory standing is defined by common law proximate causation rather than the unique bright line rule created in *Illinois Brick*. (Opp. Br. at 52–53). They argue that *Holmes* adopted a "direct-injury" requirement for RICO statutory standing "to prevent [courts from] blur[ring] the line between RICO and antitrust laws. (*Id.* at 53). Importantly, they note that in reaching this conclusion, *Holmes* addressed the same concerns as *Illinois Brick*: (i) directness between racketeering scheme and economic injury; (ii) "risk of duplicative recoveries;" and (iii) whether a "more immediate victim is better situated to sue." (Opp. Br. to CDF at 2). Finally, the

MSP Plaintiffs contend that "*Holmes* aligns with congressional intent to not incorporate antitrust standing into RICO cases." (*Id.* at 1 (citations omitted)). The Court disagrees.

In *Holmes*, the Securities Investor Protection Corporation ("SIPC") sued under RICO to recover funds it paid to creditors of two broker-dealers who went bankrupt after investing in the defendant's stock-manipulation scheme. *Holmes*, 503 U.S. at 261–63. The Supreme Court held that SIPC could not maintain its RICO claims against the defendant. The Supreme Court examined the legislative history of section 1962(c) and concluded that Congress did not intend to "allow all factually injured plaintiffs to recover." *Id.* at 266 (citation omitted). It explained that that RICO "incorporate[s] common-law principles of proximate causation" and also noted that RICO's civil provision drew its language directly from the Clayton and Sherman Acts, which had for decades been interpreted as incorporating proximate cause requirements. *Id.* at 267–68 (citations omitted). The Supreme Court stated that the requirement of proximate cause "demand[s] . . . some direct relation between the injury asserted and the injurious conduct alleged." *Id.* at 268. In finding that the alleged stock-manipulation scheme did not proximately cause the injury claimed, the Supreme Court emphasized that the plaintiff's injury was "too remote" and incidental to the broker-dealers' insolvency—which might have been attributable to any number of causes—making the plaintiff at best a "secondary victim[]" of the defendant's scheme. *See id.* at 271–74. "[A] plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts," the Court reasoned, "generally . . . stand[s] at too remote a distance to recover." *Id.* at 268–69. As other courts in this district have pointed out, the MSP Plaintiffs' "assertion that the Supreme Court's ruling in *Holmes* exempts RICO claims from standing challenges pursuant to the indirect purchaser rule is erroneous." *Sanofi*, 2019 WL 1418129, at *14. *Holmes* explicitly held that "federal jurisprudence interpreting antitrust principles govern RICO claims because

Congress modeled RICO's civil action provision on a substantially similar provision in the Clayton Act." *Id.; see also Holmes*, 503 U.S. at 267–68. Further, "[n]othing in *Holmes* undercuts the voluminous federal jurisprudence holding that courts may apply the indirect purchaser rule . . . to RICO actions with the same force as in the antitrust context." *Sanofi*, 2019 WL 1418129, at *15. As such, the MSP Plaintiffs' reliance on *Holmes* is unavailing.

Next, the MSP Plaintiffs cite to the Supreme Court's decision in *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008) to support their contention that RICO statutory standing is defined by common law proximate causation rather than the unique bright line rule created in *Illinois Brick*. (Opp. Br. at 53 n.213; Opp. Br. to CDF at 1–3). The Supreme Court's holding in *Bridge* also does not preclude the application of the indirect purchaser rule to the MSP Plaintiffs' RICO claims. That case involved parties who were regular bidders in county tax-lien auctions. *Bridge*, 553 U.S. at 642. Since the auction participants often tied for a winning bid, the county allocated parcels on a rotational basis. *Id.* at 642–43. It also prohibited bidders from using multiple agents to increase their chances of receiving a parcel. *Id.* at 643. When registering for an auction, each bidder was required to submit an affidavit that it was participating as a single bidder. *Id.* The plaintiff participants brought a RICO claim against other bidders whom they alleged had violated the single-bidder rule by using multiple agents in the auctions. *Id.* at 643–44. The defendants argued that section 1964(c) requires a RICO plaintiff to show that it relied on the defendants' fraudulent misrepresentations. *Id.* at 648. They contended that the single bidder affidavits were submitted to the county, not the plaintiffs, which meant that the plaintiffs could not have relied on any fraudulent misrepresentations contained in the affidavits. *Id.* at 649. The Supreme Court rejected the defendants' argument and observed that the "foreseeable and natural consequence of petitioners' scheme to obtain more liens for themselves [was] that other bidders would obtain

fewer liens." *Id.* at 658. It thus held that the proximate causation element of a RICO claim did not necessitate first-party reliance on the alleged misrepresentations. *Id.* at 657–58.

Unlike here, *Bridge* "does not concern the case of an indirect purchaser and does not stand for the proposition that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule." *Sanofi*, 2019 WL 1418129, at *14. As another court noted, "*Bridge* addressed only the issue of proximate causation and did not touch on or undercut *McCarthy*'s conclusion that an indirect purchaser/end-payor lacks standing to pursue RICO claims." *Indivior*, 2021 WL 3101593, at *10; *Rickman*, 2020 WL 3468250, at *10. The Sixth Circuit, in *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602 (6th Cir. 2004), discussed the distinction between (i) statutory standing under the indirect purchaser rule—addressed in *McCarthy*—and (ii) proximate causation as required to show RICO injury. It explained that (i) "[s]tanding poses a threshold question involving constitutional, prudential and . . . statutory limitations on who may sue regardless of that person's claim" while (ii) "[p]roximate cause poses a merits question involving common-law and prudential limitations on the consequences for which the law will hold a defendant accountable, regardless of the plaintiff's standing to sue." *Trollinger*, 370 F.3d at 612 (citations omitted). "The Sixth Circuit recognized that these concepts overlapped in the context of civil RICO claims, but were nonetheless distinct concepts with practical significance." *Indivior*, 2021 WL 3101593, at *10 (citing *Trollinger*, 370 F.3d at 613, 615). The *Trollinger* court emphasized that a plaintiff does not have standing to bring a RICO claim if the plaintiff suffers "derivative or passed-on injuries." *Trollinger*, 370 F.3d at 614. It noted that "a RICO case with a derivative-injury problem [*i.e.*, direct purchaser versus end-payor] is better suited to dismissal on the pleadings than a RICO case with a traditional proximate-cause problem (*e.g.*, a weak or insubstantial causal link, a lack of foreseeability, or a speculative or illogical theory of damages)."

Id. at 615. The Sixth Circuit explained this was because "a court often finds no need to look beyond the face of the complaint in order to determine that the plaintiff lacks standing because the injury was passed on by another party that had a more direct relationship with the defendant." *Id.* "Courts within [the Third Circuit] have repeatedly recognized the distinction between concepts of [i] standing under the indirect purchaser rule and [ii] proximate causation."[36] *Indivior*, 2021 WL 3101593, at *10; *see also Rickman*, 2020 WL 3468250, at *10 (noting that standing and causation are "distinct issues which require discrete analyses" under RICO); *Hu*, 2021 WL 1138123, at *3; *In re Insulin*, 2019 WL 643709, at *9–11. As such, "*Bridge* does not stand for the proposition that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule." *In re Insulin*, 2019 WL 643709, at *11.

Finally, the MSP Plaintiffs cite to the Supreme Court's decision in *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006) to support their contention that RICO statutory standing is defined by common law proximate causation rather than the unique bright line rule created in *Illinois Brick*. (Opp. Br. at 53 n.210; Opp. Br. to CDF at 2–3). Again, the Court disagrees. In *Anza*, the plaintiff steel supply company sued a competitor and its owners, alleging that the competitor did not charge sales tax to its customers and that defendants filed false tax returns with the state in order to conceal the conduct. *Anza*, 547 U.S. at 453–54. The plaintiff asserted that the defendants' unlawful conduct allowed the competitor to undercut the plaintiff's prices, which in turn harmed the plaintiff's market share. *Id*. The Supreme Court found that the causation element

[36] As the court in *Indivior* noted, the Third Circuit in *McCarthy* likewise recognized the distinction between these two concepts, albeit in the antitrust context. *Indivior*, 2021 WL 3101593, at *10 n.6. The Third Circuit in *McCarthy* remarked that standing deals with whether a particular plaintiff who can trace an injury to a violation falls within the group of plaintiffs that Congress permitted to enforce the antitrust laws and explained that such a concept is a subject to "a bright-line rule." *McCarthy*, 80 F.3d at 851 n.14. By contrast, the Third Circuit noted that proximate causation is concerned with whether a particular plaintiff's injury is too remote to warrant providing that plaintiff with a remedy. *Id.* It explained that the concept of proximate causation is "subtle and resists the use of hard-and-fast 'black letter' rules." *Id.* (citing *Merican, Inc. v. Caterpillar Tractor Co.*, 713 F.2d 958, 964 (3d Cir. 1983)).

was too attenuated because the action of offering lower prices was "entirely distinct" from the alleged RICO violation of defrauding the state through filing false tax returns. *Id.* at 458–59. The Court accordingly held that the RICO plaintiff failed to establish the element of proximate cause. *Id.* at 458. Again, *Anza* did not concern the case of an indirect purchaser, and nothing in *Anza* undercuts the voluminous federal jurisprudence holding that courts may apply the indirect purchaser rule to RICO actions with the same force as in the antitrust context.[37]

Second, citing to the Supreme Court's decision in *Sedima S.P.R.L v. Imrex Co., Inc.*, 473 U.S. 479 (1985), the MSP Plaintiffs contend that the Supreme Court has rebuffed attempts to apply antitrust standing to RICO based on Congressional intent. (Opp. Br. to CDF at 3; Opp. Br. at 53 n.212). The Court disagrees. In *Sedima*, the Supreme Court rejected the Second Circuit's conclusion that "just as an antitrust plaintiff must allege an 'antitrust injury,' so a RICO plaintiff must allege a 'racketeering injury.'" *Sedima*, 473 U.S. at 485. The Court held that it did not perceive a distinct "racketeering injury" requirement from the text of the RICO statute. *Id.* at 495. However, as the Seventh Circuit explained in *Carter v. Berger*, "*Sedima* held that the 'antitrust injury' rule of antitrust does not apply to RICO, but this is so because 'RICO injury' would be an unintelligible requirement, not because there is no parallel between the two statutes." *Carter*, 777 F.2d at 1176 (citations omitted). Additionally, the plaintiff in *Sedima* was not an indirect purchaser, and the case "does not at all mention the indirect purchaser rule," nor does it provide

[37] The MSP Plaintiffs contend that in following the Supreme Court's holdings in *Holmes*, *Anza*, and *Bridge*, the Supreme Court in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 139–40 (2014) held that proximate causation is an element of "statutory standing" and held that the plaintiffs had a cause of action despite being the "indirect victim." (Opp. Br. to CDF at 3 n.5 (citing *Lexmark*, 572 U.S. at 139–40)). *Lexmark*, however, does not support the MSP Plaintiffs' position that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule. As PAN points out (PAN Reply at 6 n.4), in *Lexmark* the Supreme Court interpreted the Lanham Act and citing to *Holmes*, *Anza*, and *Bridge* stated that a statutory cause of action is presumed to be limited to plaintiffs whose injuries are proximately caused by violations of that statute. *Lexmark*, 572 U.S. at 132–34. *Lexmark*, however, did not contradict the jurisprudence that has led to the application of the indirect purchaser rule to RICO.

any "analysis tending to suggest a preference that such [a] rule not be applied in the RICO context." *In re Insulin Pricing Litig.*, 2019 WL 643709, at *11 n.9. Accordingly, *Sedima* has no bearing on whether the indirect purchaser rule applies equally in the RICO context, and the MSP Plaintiffs' reliance on that case is unavailing.

The Court is also unpersuaded by the MSP Plaintiffs' reliance on congressional intent. The MSP Plaintiffs point out that RICO makes it unlawful to receive "any income derived, directly or *indirectly*, from a pattern of racketeering activity." (Opp. Br. to CDF at 4 (internal quotation marks omitted) (quoting 18 USC § 1962(a))). They state that RICO creates a private cause of action for "[a]ny person injured in his business or property *by reason of a violation of* [§] *1962*." (*Id.* (alterations in original) (quoting § 1964(c))). The MSP Plaintiffs emphasize that "[i]t would be contrary to the 'will of the Legislature' to apply the [indirect purchaser rule] to those *indirectly* injured by RICO violations when § 1964 makes one civilly liable to '[a]ny person' injured 'by reason of' the 'direct[] *or indirect*[]' gain of another." (*Id.*). However, clear Third Circuit precedent says otherwise. More specifically, as recounted above, in *McCarthy*, the Third Circuit unequivocally ruled that the *Illinois Brick* indirect purchaser rule applies to civil RICO claims. *McCarthy*, 80 F.3d at 855 ("The precepts taught by *Illinois Brick* . . . apply to RICO claims, thereby denying RICO standing to indirect victims."). As explained above, the Third Circuit most recently reaffirmed *McCarthy*'s holding in a non-precedential decision in *Humana*, stating that insurers that merely reimbursed prescriptions for a drug were indirect purchasers and therefore lacked RICO standing under the indirect purchaser rule, notwithstanding the statutory language the MSP Plaintiffs cite. *Humana*, 2022 WL 17718342, at *1–3. Further, *McCarthy*'s bar on indirect purchaser standing in the RICO context has also been extensively cited with approval within

district courts in the Third Circuit on multiple recent occasions. This Court will not deviate from this clear precedent based on the MSP Plaintiffs' strained reading of congressional intent.

Third, the MSP Plaintiffs contend that the Third Circuit's application of the indirect purchaser rule to RICO cases in *McCarthy* is not controlling in this case. (Opp. Br. at 53–55; Opp. Br. to CDF at 5–7). To start, the MSP Plaintiffs contend that *McCarthy* is not binding on this Court because the plaintiffs in *McCarthy* neither briefed nor contested the application of the indirect purchaser rule to RICO. (Opp. Br. at 53–54; Opp. Br. to CDF at 5–6). More specifically, they point out that the plaintiffs in *McCarthy* "conceded that 'if they lacked antitrust standing, they also lacked RICO standing.'" (Opp. Br. at 53 n.214 (citing *McCarthy*, 80 F.3d at 855)). The MSP Plaintiffs reason that because *McCarthy*'s language regarding RICO standing was not necessary to the court's holding, it is not binding on this Court. (*See* Opp. Br. at 53–54). This argument is without merit. The Third Circuit's decision in *McCarthy* spoke definitively on the fact that "[t]he precepts taught by *Illinois Brick* . . . apply to RICO claims, thereby denying RICO standing to indirect victims." *McCarthy*, 80 F.3d at 855. As other courts in this Circuit have pointed out, "[s]uch a holding was crucial to the [Third Circuit's] determination that if the plaintiffs were not 'direct purchasers' then they did not have standing to pursue their RICO claims." *Indivior*, 2021 WL 3101593, at *12. Further, the Third Circuit most recently reaffirmed *McCarthy*'s holding in *Humana*. *Humana*, 2022 WL 17718342, at *1–3. While the Third Circuit's decision in *Humana* is not precedential, the Court finds the decision persuasive in concluding that, based on *McCarthy*, "[t]he precepts taught by *Illinois Brick* . . . apply to RICO claims, thereby denying RICO standing to indirect victims." *McCarthy*, 80 F.3d at 855.

In a further attempt to avoid the Third Circuit's clear directives, the MSP Plaintiffs contend that *McCarthy*'s approach has been rejected by more recent Third Circuit precedent. (Opp Br. at

54; Opp Br. to CDF at 6). In support, the MSP Plaintiffs rely on *In re Avandia Mktg, Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015) and *St. Luke's Health Network, Inc. v. Lancaster Gen. Hospital*, 967 F.3d 295 (3d Cir. 2020). (Opp. Br. at 54; Opp. Br. to CDF at 6). The MSP Plaintiffs' reliance on *Avandia* and *Luke's Health* is unavailing. In *Avandia*, the plaintiffs—third-party payors comprised of union health and welfare funds—alleged that a defendant drug manufacturer deliberately misrepresented significant heart related safety risks associated with the drug "Avandia" and manipulated data in order to increase sales. *Avandia*, 804 F.3d at 636. The plaintiffs alleged that they included Avandia in their formularies and covered it at favorable rates for their members in reliance on the defendant's misrepresentations about Avandia's safety. *Id.* The district court held that the plaintiffs adequately alleged that the defendant proximately caused their damages but certified its decision for interlocutory appeal. *Id.* at 637. The Third Circuit affirmed, holding that "[t]he conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused [third-party payors] and [pharmacy benefit managers] to place Avandia in the formulary." *Id.* at 644. As such, the Court concluded that such allegations were a sufficient basis on which the third-party payors could satisfy the proximate cause requirement of RICO and bring such claims against the drug manufacturer. *Id.* at 645. However, as multiple courts within this Circuit have recognized, *Avandia* addressed only the issue of proximate causation, discussed above, and did not "touch on or undercut *McCarthy*'s conclusion that an indirect purchaser/end-payor lacks standing to pursue RICO claims." *Indivior*, 2021 WL 3101593, at *10; *see also Hu*, 2021 WL 1138123, at *3 (distinguishing *Avandia* noting that it did not express disagreement with *McCarthy*); *Rickman*, 2020 WL 3468250, at *10 (holding that plaintiffs, as indirect purchasers, did not have standing to

pursue a RICO claim, and recognizing that *Avandia* addressed distinct issues of proximate causation that had no bearing on standing); *In re Insulin*, 2019 WL 643709, at *9–11 (declining to find that *Avandia* precludes the application of the indirect purchaser rule to RICO claims). In fact, in *Humana*, the Third Circuit reaffirmed *McCarthy*'s holding, even after considering *Avandia*. *Humana*, 2022 WL 17718342, at *1, *4 n.32. As such, nothing in *Avandia* undercuts the voluminous federal jurisprudence holding that courts may apply the indirect purchaser rule to RICO actions.[38]

The MSP Plaintiffs' reliance on *Luke's Health* is likewise unavailing. In *Luke's Health*, a group of hospitals and their related health care networks, alleged that the defendants, another hospital and hospital system, violated RICO by submitting fraudulent claims for reimbursement that allowed them to receive an unduly inflated proportion of available funding under a state-run program for treating indigent patients. *Luke's Health*, 967 F.3d at 297–99. The Third Circuit found that the plaintiffs adequately claimed that their injury was proximately caused by the defendants' allegedly fraudulent conduct to support their RICO claims. *Id.* at 301–02. More specifically, the court explained that because the state-run program for treating indigent patients had a fixed pool of assets, the defendants' "alleged manipulation to increase their share of the limited funding necessarily resulted in [p]laintiffs receiving a decreased proportion of those assets." *Id.* at 302. As such, the court concluded that the plaintiffs adequately demonstrated proximate causation for purposes of RICO. *Id.* However, *Luke's Health* did not touch on or

[38] Apart from the fact that *Avandia* speaks to reliance and causation, not standing, the case also presents other factual differences. The *Avandia* plaintiffs were insurers who included Avandia in their formularies in direct reliance on material misrepresentations made by the defendant regarding safety risks. *Avandia*, 804 F.3d at 636. The plaintiffs' alleged injury was based on their inclusion of Avandia in their formulary decisions at favorable rates rather than covering the competitor's less expensive drugs. *Id.* Unlike here, the *Avandia* plaintiffs were not seeking recourse pursuant to payments made based on allegedly inflated prices set by a manufacturer passed down to them through the distribution chain. *Indivior*, 2021 WL 3101593, at *10. Rather, the claimed damages in *Avandia* were based on favorable formulary placement resulting from the plaintiffs' direct reliance on defendant's misrepresentations of Avandia's heart-related risks. *Avandia*, 804 F.3d at 644. As such, *Avandia* is distinguishable from the present case.

undercut *McCarthy*'s conclusion that an indirect purchaser/end-payor lacks standing to pursue RICO claims. *See Hu*, 2021 WL 1138123, at *3 (distinguishing *Luke's Health* noting that it did not express disagreement with *McCarthy*). Unlike here, *Luke's Health* does not concern the case of an indirect purchaser and does not stand for the proposition that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule.[39]

Finally, the MSP Plaintiffs contend that *McCarthy* is inapplicable here because the indirect purchaser rule applies only to "pass-on" injuries. (Opp. Br. at 54–55; Opp. Br. to CDF at 6–7). They contend that their RICO claims are not premised on passed on overcharges. (Opp. Br. to CDF at 7). Rather, they assert that the Celgene Defendants' and Charity Defendants' co-pay scheme was not completed and no injury existed until they caused the MSP Plaintiffs' Assignors to pay for claims that were tainted by Anti-Kickback Statute violations. (Opp. Br. at 54–55; Opp. Br. to CDF at 6–7). As such, they assert that their Assignors were the "first and only entities injured by the RICO scheme." (Opp. Br. at 55; Opp. Br. to CDF at 7). In other words, the MSP Plaintiffs argue that *Illinois Brick* is inapplicable because their claims are not indirect purchaser claims, "as there are not 'multiple parties at different levels of a distribution chain [] trying to all recover the same passed-through overcharge initially levied by the manufacturer at the top of the chain.'" (Opp. Br. to CDF at 7). Rather, they assert that they are the direct and perhaps only

[39] The MSP Plaintiffs also cite to the Third Circuit's decision in *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 932–34 (3d Cir. 1999) to support their contention that RICO statutory standing is defined by common law proximate causation rather than the unique bright line rule created in *Illinois Brick*. (Opp. Br. to CDF at 2). Their reliance on *Steamfitters* is unavailing. In that case, the Third Circuit considered whether a health and welfare fund could hold tobacco companies liable under the antitrust laws and RICO for injuries caused to their members and beneficiaries. *Steamfitters*, 171 F.3d at 918. In dismissing the plaintiffs' RICO claims, the Third Circuit explained that "much (if not all) of what [it] ha[s] said above in our discussion of antitrust standing applies to the [plaintiffs'] RICO claims." *Id.* at 932. The Third Circuit also discussed "the specific requirements for stating a claim under RICO, to better explicate [its] reasons for finding that all of plaintiffs' claims must fail for being too remote and speculative." *Id.* The Third Circuit did not undermine its holding in *McCarthy* but rather expanded as to why plaintiffs could not maintain a RICO claim against the tobacco companies. Likewise, the MSP Plaintiffs' citation to *In re Processed Egg Prod. Antitrust Litig.*, 881 F.3d 262 (3d Cir. 2018) is unavailing (Opp. Br. to CDF at 7 n.9), since there the Third Circuit noted that unlike *Illinois Brick*, the plaintiffs in that case were in a direct purchaser relationship with the defendants. *In re Processed Egg*, 881 F.3d at 275.

victims and targets of the Celgene Defendants' and Charity Defendants' fraud. (Opp. Br. to CDF at 7; *see* Opp. Br. at 55). This argument is without merit. Faced with similar arguments in *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 92 (3d Cir. 2011), the Third Circuit noted that *Illinois Brick* and its progeny

> [D]id not resolve what party was a direct purchaser by calculating exactly where the harm lay. In fact, the [Supreme] Court's discussion in those cases of the policy rationales underpinning the rule manifests the Court's intent to *avoid* linking direct purchaser status to injury calculations in determinations. In *UtiliCorp*, the consumer plaintiffs also argued that the public utility (the direct purchaser) had not been harmed by the antitrust defendant's actions, and that consumers had borne the full brunt of the injuries, thus justifying an exception to the *Illinois Brick* rule. The Court highlighted the need to apply the rule consistently: "[T]he process of classifying various market situations according to the amount of pass-on likely to be involved and its susceptibility of proof in a judicial forum would entail the very problems that the [indirect purchaser] rule was meant to avoid. The litigation over where the line should be drawn in a particular class of cases would inject the same massive evidence and complicated theories into treble-damages proceedings, albeit at a somewhat higher level of generality."

643 F.3d 77, 92 (3d Cir. 2011) (quoting *UtiliCorp*, 497 U.S. at 216–17). Based on the Third Circuit's teachings in *Warren*, which emphasized that the indirect purchaser rule admits no exceptions, the Court finds that there are no "direct injury" or "only victim" exceptions to the indirect purchaser rule. *Id.*; *see also Hu*, 2021 WL 346974, at *4 (holding that there is no direct-harm exception to the indirect purchaser rule). As such, the MSP Plaintiffs' assertion that *Illinois Brick* is inapplicable because their claims are not true indirect purchaser claims is unpersuasive.[40]

[40] In support of their argument that the indirect purchaser rule applies only to "pass-on" injuries, the MSP Plaintiffs cite to the Supreme Court's decision in *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1521 (2019), stating that the Supreme Court in *Apple* refused to apply *Illinois Brick* because the plaintiffs did not rely on a pass-on theory, despite the presence of intermediate actors in the supply chain. (Opp. Br. at 54–55; Opp. Br. to CDF at 7). However, in *Apple*, the plaintiffs were, in fact, direct purchasers of the products at issue. *Id*. at 1521. (Reply at 28; CDF Reply at 4 n.8). Here, it is clear that the MSP Plaintiffs and their Assignors were not direct purchasers of Revlimid or Thalomid. As such, the MSP Plaintiffs' reliance on *Apple* is unavailing. Further, the MSP Plaintiffs citation to an out of district

The bright-line indirect purchaser rule, as articulated in *Illinois Brick* and applied to RICO cases in *McCarthy* and again in *Humana*, bars the MSP Plaintiffs' RICO claims. As the Supreme Court recently explained, the rule is simple and straightforward. *See Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1521 (2019) ("[I]f manufacturer A sells to retailer B, and retailer B sells to consumer C, then C may not sue A."). It noted that "the bright-line rule of *Illinois Brick* means that there is no reason to ask whether the rationales of *Illinois Brick* 'apply with equal force' in every individual case" as it is unwise to "engage in 'an unwarranted and counterproductive exercise to litigate a series of exceptions.'" *Id.* at 1524 (quoting *UtiliCorp*, 497 U.S. at 216–17). As such, because the MSP Plaintiffs' Assignors did not purchase Revlimid or Thalomid directly from Celgene, the MSP Plaintiffs' RICO claims must be dismissed *with prejudice* pursuant to the indirect purchaser rule.[41] *Indivior*, 2021 WL 3101593, at *12.

court case (Opp. Br. to CDF at 2 n.4), does not alter the Court's conclusion to dismiss their RICO claims pursuant to the indirect purchaser rule, which is warranted based on clear Third Circuit precedent.

[41] In addition to damages, the MSP Plaintiffs also appear to seek injunctive/equitable relief under RICO. (MSP SAC ¶¶ 613 & 626). Neither the Supreme Court nor the Third Circuit have considered whether equitable relief is available to private parties under RICO. *RJR Nabisco, Inc. v. European Community*, 579 U.S. 325, 354 n.13 (2016) ("This Court has never decided whether equitable relief is available to private RICO plaintiffs, the parties have not litigated that question here, and we express no opinion on the issue today."); *Steamfitters*, 171 F.3d at 935 n.20 ("This court has yet to decide whether injunctive relief is available for a private party under RICO." (citing *Conkling v. Turner*, 18 F.3d 1285, 1296, 1296 n.8 (5th Cir. 1994))). However, several courts in this District have determined that private parties cannot obtain equitable relief under RICO. *See, e.g.*, *Minnesota by Ellison*, 2020 WL 2394155, at *11–12 (holding "that a private party may not seek equitable relief under RICO"); *MSP Claims Recovery Series, LLC v. Sanofi-Aventis U.S. LLC*, No. 18-2211, 2020 WL 831578, at *7–8 (D.N.J. Feb. 20, 2020). Regardless, in interpreting section 1964, courts have held that a private plaintiff must still prove a violation of section 1962 to obtain equitable relief. *See Chevron Corp. v. Donziger*, 833 F.3d 74, 137 (2d Cir. 2016) ("We conclude that a federal court is authorized to grant equitable relief to a private plaintiff who has proven injury to its business or property by reason of a defendant's violation of § 1962 . . . "); *see also Aliperio v. Bank of Am., N.A.*, No. 16-1008, 2016 WL 7229114, at *15 n.16 (D.N.J. Dec. 13, 2016). As discussed, the MSP Plaintiffs cannot proceed with a RICO claim against the Celgene Defendants and Charity Defendants under section 1962 pursuant to the indirect purchaser rule. As such, the MSP Plaintiffs are similarly unable to seek equitable relief for the alleged RICO violations. *Abbott*, 2021 WL 2177548, at *9. Accordingly, to the extent the MSP Plaintiffs seek injunctive/equitable relief under RICO, their claims for injunctive/equitable relief are likewise dismissed.

Finally, because the Court finds that the MSP Plaintiffs' RICO claims must be dismissed for lack of standing pursuant to the indirect purchaser rule the Court does not consider the Celgene Defendants' and Charity Defendants' remaining arguments in favor of dismissing these claims. (Mov. Br. at 52–53; CDF Mov. Br. at 12–30; PAN Mov. Br. at 26–34).

C. Sherman Act Claims

The Court will next analyze the sufficiency of the Insurer Plaintiffs' and MSP Plaintiffs' Sherman Act claims. The Insurer Plaintiffs and MSP Plaintiffs bring claims against the Celgene Defendants under Section 2 of the Sherman Act. (Humana Am. Compl. ¶¶ 582–87 & 627–35; MSP SAC ¶¶ 575–82). As described above, to support their Section 2 claim, the Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants engaged in a course of conduct to delay and stunt generic competition and extend their monopoly power in the Revlimid market by (i) refusing to sell or otherwise provide samples of Revlimid to generic manufacturers for bioequivalency testing, (ii) entering into an anticompetitive settlement agreement, (iii) fraudulently procuring patents, (iv) and improperly filing sham lawsuits against generic manufacturers seeking to compete and improperly listing patents in the Orange Book. (Opp. Br. at 13–14). In addition, the MSP Plaintiffs also bring a Section 2 claim against the Celgene Defendants based on allegations that Celgene refused to sell or otherwise provide samples of Thalomid to generic manufacturers for bioequivalency. Finally, the MSP Plaintiffs bring a Section 2 claim against the Celgene Defendants based on allegations that Celgene made unlawful donations to the Charity Defendants to fund patient co-pays of Thalomid and Revlimid.[42]

To state a plausible claim for relief under Section 2 of the Sherman Act, a plaintiff must show that the defendant (i) possessed "monopoly power in the relevant market" and (ii) willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Broadcom Corp. v. Qualcomm Inc.*,

[42] As specified above, Humana and Cigna are the only Insurer Plaintiffs that are bringing suit as direct purchasers on behalf of certain assignees, and thus assert a claim for damages under Section 2. (Humana Am. Compl. ¶¶ 582–87; *Cigna Corp. v. Celgene Corp.*, 21-11868, (D.E. No. 40 ¶¶ 582–87)). The remainder of the Insurer Plaintiffs whose Operative Complaints are being addressed in this Opinion are bringing suit as indirect purchasers and as such are only bringing their Section 2 claim for declaratory and injunctive relief.

501 F.3d 297, 307 (3d Cir. 2007) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)) (internal quotation marks omitted). Here, the parties' disputes regarding the sufficiency of the Insurer Plaintiffs' and MSP Plaintiffs Section 2 Sherman act claims turns on the second element, also known as the requirement of "anticompetitive" or "exclusionary" conduct.

The Insurer Plaintiffs also bring claims against the Celgene Defendants under Section 1 of the Sherman Act. (Humana Am. Compl. ¶¶ 570–81 & 627–35). More specifically, the Insurer Plaintiffs allege that the Celgene Defendants violated Section 1 of the Sherman Act by entering into an anticompetitive settlement agreement with Natco. (*Id.* ¶ 571).

Section 1 declares as illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. Section 1 is interpreted to outlaw "unreasonable restraints" on trade. *Ohio v. Am. Express Co.*, 585 U.S. 529, 540 (2018) (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)) (formatting modified). To plead a claim under Section 1, a plaintiff must allege: (i) the existence of an agreement and (ii) that the agreement unreasonably restrains trade. *See Am. Needle, Inc. v. NFL*, 560 U.S. 183, 190 (2010) (citations omitted).

i. Anticompetitive Scheme

As noted above, the Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants took a series of actions in furtherance of an overall scheme to violate Section 2 of the Sherman Act. (Opp. Br. at 13–14; Humana Am. Compl. ¶ 1; MSP SAC ¶ 8). The Celgene Defendants attack the sufficiency of each one of these sets of allegations. (*See generally* Mov. Br.). In response, the Insurer Plaintiffs and MSP Plaintiffs argue that the Celgene Defendants' motion improperly seeks to slice-and-dice the antitrust allegations into various isolated sub-claims or acts, despite the fact that the Insurer Plaintiffs and MSP Plaintiffs do not plead them as free-

standing counts. (Opp. Br. at 14–15). They argue that they have alleged that the Celgene Defendants took a series of actions in furtherance of an overall scheme to violate the antitrust laws. (*Id.* at 13). More specifically they argue that they plausibly allege that Celgene and, later BMS, delayed and stunted generic competition through a scheme that consisted of, *e.g.*, (i) citing the REMS safety programs as a pretext for refusing to sell generics samples; (ii) paying off the first-to-file, would-be generic competitor through a secret, "pay-for-delay" settlement agreement and reinforcing the first-to-file payoff through later settlements with later would-be generics; (iii) obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; and (iv) prosecuting over a dozen patent litigations where they had no realistic likelihood of prevailing on the merits. (*Id.* at 13–14). They contend that courts permit scheme claims "even in the absence of allegations that each of the scheme's predicate actions was independently violative of antitrust laws." (*Id.* at 13). The Celgene Defendants disagree, arguing that the Court can properly consider the individual aspects of the Insurer Plaintiffs' and MSP Plaintiffs' scheme because if "alleged instances of misconduct are not independently anti-competitive . . . they are not cumulatively anti-competitive either." (Reply Br. at 4 (citing *Eatoni Ergonomics, Inc. v. Rsch. in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012)). For the reasons set forth below, the Court agrees with the Celgene Defendants' approach.

In antitrust cases in which a scheme is alleged, "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698–99 (1962); *see also In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 261 (D. Mass. 2017). In fact, the Third Circuit has held that "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d

141, 162 (3d Cir. 2003). "It is the mix of various ingredients . . . in a monopoly broth that produces the unsavory flavor." *City of Mishawaka v. Am. Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980). Nevertheless,

> [a]t the same time, if all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing. Similarly, a finding of some slight wrongdoing in certain areas need not by itself add up to a violation. We are not dealing with a mathematical equation. We are dealing with what has been called the 'synergistic effect' of the mixture of the elements.

City of Anaheim v. S. California Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) (quoting *City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 929 (2d Cir. 1981)).

When faced with allegations of a broad antitrust scheme, multiple courts, including within our Circuit, have found that it is appropriate to consider the individual components of the scheme and whether those components can substantiate a claim of anticompetitive conduct on their own, as long as the larger scope of the scheme is kept in context. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-2445, 2017 WL 3967911, at *8 n.10 (E.D. Pa. Sept. 8, 2017); *Asacol*, 233 F. Supp. 3d at 261 (collecting cases); *Crowder v. LinkedIn Corp.*, No. 22-0237, 2023 WL 2405335, at *3 (N.D. Cal. Mar. 8, 2023). The Third Circuit appears to have approved the soundness of this approach in *In re Processed Egg Prod. Antitrust Litig.*, 962 F.3d 719 (3d Cir. 2020), in the context of a conspiracy claim under Section 1 of the Sherman Act. There, though the Third Circuit acknowledged the Supreme Court's admonition in *Continental Ore* against "compartmentalizing . . . various factual components" in an antitrust case, it stated that this admonition was "given in relation to a lower court's assessment of the sufficiency of evidence at a trial, and the direction given was definitely not that the various stratagems of an alleged conspiracy must be evaluated under a single standard." *In re Processed Egg*, 962 F.3d at 727. As such, the Third Circuit emphasized that "*Continental Ore* does not require analysis of the

distinct components of a conspiracy as if they were an undifferentiated and indistinguishable bunch of behaviors" and stated that "[c]ourts can consider the differing components of an alleged conspiracy separately when determining which mode of antitrust analysis to apply." *Id.* at 727–28; *see also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 760 (D.N.J. 1999) ("Indeed, where numerous claims of anticompetitive conduct are set forth in support of a Sherman Act claim, many courts, including the Supreme Court itself in *Continental Ore*, have addressed the allegations separately in order to facilitate an orderly evaluation of the objections raised.").

Further, the Third Circuit has stated that "[t]he relevant inquiry is the anticompetitive effect of [a defendant's] *exclusionary* practices considered together." *LePage's Inc.*, 324 F.3d at 162 (emphasis added). "Logically, then, if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate" the Sherman Act. *Suboxone*, 2017 WL 3967911, at *8 n.10; *see Eatoni Ergonomics, Inc. v. Rsch. in Motion Corp*., 486 Fed. App'x. 186, 191 (2d Cir. 2012). As such, where a plaintiff has failed to demonstrate that any action was independently anticompetitive, courts have found that there can be no overarching anticompetitive scheme. *See Eatoni*, 486 Fed. App'x. at 191 ("[When] alleged instances of misconduct are not independently anti-competitive . . . they are not cumulatively anticompetitive either."); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14–02503, 2015 WL 5458570, at *13 (D. Mass. Sept. 16, 2015) (concluding that a complaint failed to state a Section 2 claim under an "overarching scheme" theory when none of the alleged conduct was independently anticompetitive); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1366–67 (Fed. Cir. 1999) (same). Consistent with the approach taken by courts within and outside of the Circuit, this Court will consider the individual components and theories of liability that support the Insurer Plaintiffs' and MSP Plaintiffs'

Sherman Act claims to determine their sufficiency, while also keeping the larger scope of the scheme in context and ruminating upon the effect of combining those components. *Intergraph*, 195 F.3d at 1366–67 ("Each legal theory must be examined for its sufficiency and applicability, on the entirety of the relevant facts."). Nevertheless, for the reasons set forth below, even considering the claims in the context of a larger scheme, the Court finds that they do not sufficiently allege anticompetitive conduct when considered independently or in tandem. *City of Anaheim*, 955 F.2d at 1376.

ii. The Refusal to Deal Allegations

The Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act in part by refusing to sell samples of Revlimid to generic manufacturers for bioequivalency testing, thus inhibiting the development of generic versions of that drug. The MSP Plaintiffs also allege that the Celgene Defendants violated Section 2 of the Sherman Act in part by refusing to sell samples of Thalomid to generic manufacturers for bioequivalency testing, thus inhibiting the development of generic versions of that drug.[43] The Court will begin by analyzing whether this component of the overall scheme can on its own support a claim under Section 2 of the Sherman Act based on a refusal to deal. For the reasons set forth below, the Court finds that it cannot.

The Celgene Defendants move to dismiss the Insurer Plaintiffs' and MSP Plaintiffs' Operative Complaints insofar as they allege that Celgene acted anticompetitively by refusing to sell samples of Revlimid to generic manufacturers for bioequivalency testing, thus inhibiting the

[43] As recounted above, the Insurer Plaintiffs are not pursuing any stand-alone claims based on Celgene's conduct related to Thalomid. (Opp. Br. at 2 n.1; Tr. of Aug 18, 2023 Oral Arg. at 31:10–16). Accordingly, they only bring allegations regarding Celgene's anticompetitive conduct in refusing to provide generic competitors with samples of Revlimid. In contrast, the MSP Plaintiffs bring allegations regarding Celgene's alleged refusal to provide its generic competitors with samples of Thalomid *and* Revlimid.

development of generic versions of that drug. (Mov. Br. at 43–50). Likewise, the Celgene Defendants move to dismiss the MSP Plaintiffs' Second Amended Complaint insofar as they allege that Celgene acted anticompetitively by refusing to sell samples of Thalomid to generic manufacturers for bioequivalency testing, thus inhibiting the development of generic versions of that drug. (*Id.*). *First*, the Celgene Defendants contend that a Section 2 Sherman Act claim based on a refusal to deal is only viable where that refusal terminated a prior course of dealing. (*Id.* at 44). According to the Celgene Defendants, every federal Circuit Court to have considered the question—including the Second, Sixth, Eighth, Tenth, Eleventh, and D.C. Circuits, as well as the Seventh Circuit in dicta—have rejected the viability of a refusal to deal claim absent a prior course of dealing. (*Id.* at 45 n.16 (collecting cases)). The Celgene Defendants acknowledge that this Court has previously held that the termination of a preexisting course of dealing is not required to plead a viable antitrust refusal to deal claim. (*Id.* at 48 (citing *Mylan Pharms. v. Celgene Corp.*, No. 14-2094, 2014 WL 12810322, at *4–6 (D.N.J. Dec. 23, 2014)). Nevertheless, the Celgene Defendants now ask the Court to reconsider its prior conclusion, given the continued evolution of the law in this area indicating that a Section 2 Sherman Act claim based on a refusal to deal is not viable absent a prior course of dealing. (*Id.* at 48–49). Because the Insurer Plaintiffs and MSP Plaintiffs do not allege that Celgene terminated a prior voluntary course of dealing with its competitors in refusing to sell samples of Revlimid or Thalomid to them, the Celgene Defendants contend that their refusal to deal theory is not cognizable. (*Id.* at 44–49).

Second, the Celgene Defendants additionally argue that the Insurer Plaintiffs and MSP Plaintiffs fail to state a claim as to Celgene's alleged refusal to sell Revlimid samples because Celgene had a legitimate business justification for refusing to provide such samples to generic competitors before they had obtained FDA approval of their study protocols. (*Id.* at 49). They

point out that the Insurer Plaintiffs and MSP Plaintiffs have failed to allege that any competitor, other than Mylan, had provided to Celgene proof of FDA approval of its study protocols for Revlimid before requesting samples. (*Id.*). As such, the Celgene Defendants argue that they cannot be subject to antitrust liability for refusing to deal with those competitors who failed to obtain FDA approval of their study protocols. (*Id.*). In support of this argument, the Celgene Defendants point out that on summary judgment in a suit brought by Mylan against Celgene, this Court held that "until Celgene was informed about the FDA's approval of Mylan's testing protocols for either [Thalomid or Revlimid]—no reasonable jury c[ould] infer that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid or Revlimid." *Mylan Pharms. Inc. v. Celgene Corp.*, No. 14-2094, 2018 WL 11299447, at *15 (D.N.J. Oct. 3, 2018); (Mov. Br. at 49). As such, because this Court previously held that Celgene had an objectively legitimate business justification for requiring FDA approval of study protocols before turning over Revlimid samples, the Celgene Defendants argue that they cannot be subject to antitrust liability, as against those competitors who failed to obtain such approvals, as a matter of law. (Mov. Br. at 49–50).

The Insurer Plaintiffs and MSP Plaintiffs oppose the Celgene Defendants' motion. *First*, the Insurer Plaintiffs and MSP Plaintiffs argue that the Supreme Court has never held that the termination of a preexisting course of dealing is necessary to state an antitrust claim under Section 2 of the Sherman Act, and as such the Celgene Defendants' insistence on engrafting a prior course of dealing requirement into a Section 2 claim is not supported by law. (Opp. Br. at 44). *Second*, the Insurer Plaintiffs and MSP Plaintiffs argue that the Court should reject the Celgene Defendants' meritless attack on the sufficiency of their refusal to deal allegations. (*Id.* at 48–49). In particular, they point out that this Court's prior decision in finding that Celgene had an objectively legitimate

business justification for requiring FDA approval of study protocols before turning over Revlimid samples was made on a motion for summary judgment, and thus should not be used to evaluate the sufficiency of their pleadings at this stage. (*Id.* at 48). Further, they contend that it was company policy for Celgene to refuse to provide samples of its drugs to all generics, regardless of FDA approval. (*Id.* at 48 n.185). For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that the Insurer Plaintiffs and MSP Plaintiffs have failed to state a viable Section 2 Sherman Act claim based on a refusal to deal.

"As a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009). Even the earliest Section 2 cases note that the Sherman Act "does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). This general no-duty-to-deal rule applies even where a monopolist refuses to deal with its competitor merely "in order to limit entry." *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004); *see also Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 375–76 (7th Cir. 1986) ("Today it is clear that a firm with lawful monopoly power has no general duty to help its competitors" and thus no duty "to extend a helping hand to new entrants . . . [or] help [rivals] . . . survive or expand . . . ."); *Aerotec Int'l, Inc. v. Honeywell Int'l, Inc.*, 836 F.3d 1171, 1184 (9th Cir. 2016) (rejecting argument that refusal to deal is unlawful because it was motivated by "intent to foreclose competition"). Requiring a business to cooperate with competitors "is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, rival, or both" to innovate. *Trinko*, 540 U.S. at 407–08. "Courts are ill suited 'to act as central planners,

identifying the proper price, quantity, and other terms of dealing.'" *Linkline*, 555 U.S. at 452 (quoting *Trinko*, 504 U.S. at 408). Of most concern is that forced cooperation and negotiation between competitors may facilitate "the supreme evil of antitrust: collusion." *Trinko*, 540 U.S. at 408. Nevertheless, the high value placed on the right to refuse to deal with other firms does not mean that the right is unqualified, and an affirmative duty to deal may arise under certain limited circumstances. *See id.* at 398, 408; *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985). However, a Sherman Act violation for a refusal to deal is "near the outer boundary of [Section] 2 liability." *Trinko*, 540 U.S. at 409.

"The leading case for [Section] 2 liability based on refusal to cooperate with a rival" is *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985). *Id.* at 408. There, the Supreme Court considered a course of dealing between two companies that owned ski resorts in Aspen. *Aspen Skiing Co.*, 472 U.S. at 587. Beginning in 1962, Aspen Skiing and Highlands cooperated to sell skiers an interchangeable ticket that could be used on any of the four mountains in Aspen. *Id.* at 587–89. For over fifteen years, the two companies worked together to issue passes that covered both companies' mountains and divided the profits according to the percentage of skiers that visited a particular mountain. *Id.* at 591. However, in 1978, Aspen Skiing decided to discontinue the 4-area ticket unless Highlands would accept a 12.5% fixed percentage of the revenue, which was lower than the usage of its mountain. *Id.* at 592. When Highlands refused to accept those terms, Aspen Skiing began selling a pass covering only its three mountains. And when Highlands attempted to purchase Aspen Skiing's lift tickets to create a multi-pass on its own, Aspen Skiing refused to sell to Highlands, even at retail price. *Id.* at 592–94. Highlands then brought an antitrust claim under Section 2, arguing that Aspen Skiing had monopolized the market for downhill skiing in Aspen. *Id.* at 595. The Supreme Court held that the right to refuse to deal

was not unqualified and found that a reasonable jury could find that Aspen Skiing's conduct was exclusionary. *Id.* at 587–95. This conclusion was supported by a number of factors. To start, the Supreme Court relied upon the fact that Aspen Skiing "elected to make an important change in a pattern of distribution" that had originated in a competitive market and that had persisted for several years. *Id.* at 603. Such a pre-existing relationship supported a presumption that the joint arrangement was efficient and profitable, and Aspen Skiing's decision to terminate that relationship indicated that the defendant's conduct was not "justified by any normal business purpose." *Id*. at 608. To the contrary, it indicated that Aspen Skiing "elected to forgo [ ] short-run benefits because it was more interested in reducing competition in the Aspen market over the long run." *Id.* Further, the Court noted that there was significant consumer demand for the four-mountain pass and many consumers felt that they could not visit the mountain of their choice once that pass had been eliminated. The Court determined that by refusing to sell Highland any of its lift tickets, even at retail price, Aspen Skiing's sole motivation was to harm Highlands. *Id.* at 601, 605–09. As such, the Supreme Court created an exception to the no duty to deal rule in *Aspen Skiing* by holding that a defendant violated section 2 when it terminated a long-standing, profitable business relationship in which the parties offered joint ski passes to both parties' ski mountains. *Id*. at 587–95.

The Supreme Court revisited *Aspen Skiing* nearly twenty years later in *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP,* 540 U.S. 398 (2004). In *Trinko* the plaintiffs alleged that the defendant, Verizon, violated Section 2 of the Sherman Act by refusing to provide its competitors with access to its communication network, conduct for which the government had penalized Verizon under the Telecommunications Act of 1996. The Supreme Court rejected the plaintiffs' claim, declining to extend *Aspen Skiing* to Verizon's conduct. *Trinko,* 540 U.S. at 409–

10. It held that "*Aspen Skiing* is at or near the outer boundary of [Section] 2 liability," and proceeded to distinguish *Aspen Skiing* on a series of facts. *Trinko*, 540 U.S. at 409. Significantly, the Supreme Court explained that, in *Aspen Skiing*, the "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Id.* (emphasis in original). In *Trinko*, on the other hand, the complaint did not allege that Verizon ever engaged in a voluntary course of dealing with its rivals, and therefore its prior conduct shed no light upon whether its lapses from the legally compelled dealing were anticompetitive. *Id.* *Trinko* also distinguished itself from *Aspen Skiing* on the grounds that, in *Aspen Skiing*, the defendant refused to sell a product to its competitor at retail price even though it had sold it at that price to other similarly situated customers. *Id.* This fact was further indicative of anticompetitive conduct and missing from the record in *Trinko*. *Id.* Finally, the *Trinko* Court concluded that the antitrust laws did not create a duty to deal in the circumstances of that case, as they provided little additional benefit to the regulations already in place. The Court noted that "[w]here such a [regulatory] structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny." *Id.* at 412. As such, the *Trinko* Court made clear that the "regulatory context . . . may also be a consideration in deciding whether to recognize an expansion of the contours of [Section] 2." *Id.*

In the wake of *Trinko*, multiple courts in this Circuit and outside of this Circuit have examined three main factors in determining whether a plaintiff has adequately stated a Section 2 Sherman Act claim based on a refusal to deal: (i) whether there is a preexisting voluntary and presumably profitable course of dealing between the alleged monopolist and rival with which the monopolist later refuses to deal; (ii) whether the discontinuation of the preexisting course of

dealing suggests a willingness by the alleged monopolist to forsake short-term profits to achieve an anti-competitive end, rather than to advance a valid business purpose; and (iii) whether the refusal to deal involves products that the alleged monopolist already sells in the existing market to other similarly situated customers. *See, e.g.*, *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1074–75 (10th Cir. 2013); *FTC v. Qualcomm Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020); *Blix Inc. v. Apple, Inc.*, No. 19-1869, 2020 WL 7027494, at *7 (D. Del. Nov. 30, 2020); *SEI Glob. Servs., Inc. v. SS&C Advent*, 496 F. Supp. 3d 883, 897 (E.D. Pa. 2020), *aff'd*, No. 20-3386, 2022 WL 2356730 (3d Cir. June 30, 2022); *New York v. Facebook, Inc.*, 549 F. Supp. 3d 6, 27 (D.D.C. 2021), *aff'd sub nom. New York v. Meta Platforms, Inc.*, 66 F.4th 288 (D.C. Cir. 2023). In addition, courts will consider the "regulatory context" in "deciding whether to recognize an expansion of the contours of [Section] 2." *Trinko*, 540 U.S. at 412; *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 687 (E.D. Pa. 2014).

The Celgene Defendants contend that in light of the Supreme Court's decisions in *Aspen Skiing* and *Trinko*, and numerous Circuit Court cases interpreting those decisions, the Insurer Plaintiffs and MSP Plaintiffs *must* allege that Celgene terminated a prior course of dealing with a competitor in order to state a Section 2 Sherman Act claim based on a refusal to deal. Based on the weight of authority in this area, the Court agrees and finds that the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot fall even "at or near the outer boundary of [Section] 2 liability" without alleging the unilateral termination of a voluntary and profitable course of dealing, which suggests a willingness to forsake short-term profits to achieve an anti-competitive end. *Trinko*, 540 U.S. at 409.

As discussed, in *Trinko*, the Supreme Court clarified that *Aspen Skiing* embodies only a "limited exception" to the general rule that firms may choose other companies with which they

deal. *Id.* One of the factors that the Supreme Court in *Trinko* highlighted as significant in finding that *Aspen Skiing* "was at or near the outer boundary of Section 2 liability" was the "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing [which] suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Id.* In other words, the Supreme Court reasoned that a prior course of dealing was significant in determining whether the defendant's conduct fell within *Aspen Skiing*'s limited exception. It does not appear that the Third Circuit has ever directly considered whether a plaintiff must allege that a defendant terminated a prior course of dealing with a competitor in order to state a viable Section 2 Sherman Act claim based on a refusal to deal. Nevertheless, at least two Third Circuit decisions are instructive in the Court's analysis of this issue.

The first is *BroadCom Corp. v. Qualcomm Incorp.*, 501 F.3d 297 (3d Cir. 2007). *Broadcom* involved two mobile wireless telephone companies, Broadcom Corporation ("Broadcom") and Qualcomm, Inc. ("Qualcomm"). Broadcom alleged that Qualcomm falsely represented that it would license its patented mobile wireless technology to competitors on "fair, reasonable, and non-discriminatory" ("FRAND") terms. *BroadCom Corp.*, 501 F.3d at 304. Qualcomm allegedly made this representation to a private industry group known as a "standards-determining organization" ("SDO") which in turn included Qualcomm's technology in an industry wide standard on the basis of Qualcomm's representation. *Id.* Qualcomm, however, then allegedly licensed the technology on non-FRAND terms, locking in its competitors at monopoly prices. *Id.* Though the Third Circuit acknowledged that *BroadCom* was not a strict "refusal to deal" case, it noted in dicta that if it "were to analyze it as such, [it] would find that the [c]omplaint does not run afoul of established Supreme Court precedent" because the limited exception to the "no duty to deal" rule applied. *Id.* at 316. The Third Circuit explained that the Supreme Court "created an

exception to this [no duty to deal] rule by holding that the decision of a defendant who possessed monopoly power to terminate a voluntary agreement with a small rival evidenced the defendant's willingness to forego short-run profits for anticompetitive purposes." *Id.* (citing *Aspen Skiing*, 472 U.S. at 610–11) (emphasis added). Though the plaintiff in *BroadCom* did not allege that Qualcomm ever actually licensed to its rivals in the past, the Third Circuit found that Qualcomm's anticompetitive conduct was more similar to *Aspen Skiing* than *Trinko*. More specifically, the Third Circuit explained that Broadcom's complaint alleged that Qualcomm had "actively marketed its [] technology for inclusion in an industry-wide standard," and that Qualcomm had "voluntarily agreed to license that technology on FRAND terms." *Id.* According to the Third Circuit, Qualcomm's voluntary participation in the standard setting process, and Qualcomm's voluntary commitment to license its technology on FRAND terms, constituted a voluntary course of conduct that distinguished Qualcomm's conduct from Verizon's conduct in *Trinko*, where the complaint "did not allege that [Verizon] engaged in a voluntary course of dealing with its rivals, or would have done so absent statutory compulsion." *Id.* In other words, while the plaintiff in *Broadcom* did not allege a prior course of dealing between Qualcomm and its rivals, it did allege, unlike *Trinko*, that Qualcomm voluntarily agreed to license its technology on FRAND terms and altered that voluntary course of conduct, which appeared to be relevant as "evidence[ ] [of] the defendant's willingness to forego short-run profits for anticompetitive purposes." *Id.*

Also instructive is the Third Circuit's decision in *Host Int'l, Inc. v. MarketPlace, PHL, LLC*, 32 F.4th 242 (3d Cir. 2022). In *Host Int'l*, after a competitive bidding process, Host won two concession spots at Philadelphia International Airport ("PHL") and planned to open a coffee shop in one and a restaurant in the other. *Host Int'l*, 32 F.4th at 247. Negotiations between Host and MarketPlace, the real estate company that was a landlord for PHL, stalled when MarketPlace

insisted on a term allowing it to enter into certain agreements granting third parties exclusive or semi-exclusive rights to be the sole providers of certain foods, beverages, or other products at the airport's concession stands. *Id.* This included a pouring-rights agreement ("PRA") granting a beverage manufacturer, bottler, distributor, or other company exclusive control over the beverages advertised, sold, and served at PHL. *Id.* Host demanded that the PRA be excluded from the lease agreement. *Id.* When MarketPlace refused, Host rejected the leases and ended negotiations. *Id.* Subsequently, Host sued MarketPlace under Section 1 of the Sherman Act. *Id.* Notably, the plaintiff in *Host* did not bring a Section 2 Sherman Act claim premised on a refusal to deal. Nevertheless, in dicta, the Third Circuit acknowledged that refusing to deal can sometimes establish an antitrust claim under Section 2, but "only among competitors, *and only if the parties have a history of dealing* paired with facts suggesting 'a willingness to forsake short-term profits to achieve an anticompetitive end.'" *Host Int'l, Inc.*, 32 F.4th at 250 n.7 (emphasis added).

As discussed, neither *Broadcom* nor *Host* directly considered whether a plaintiff must allege that a defendant terminated a prior course of dealing with a competitor in order to state a Section 2 Sherman Act claim based on a refusal to deal. However, *Broadcom* at least suggests that an alteration in a voluntary course of conduct is significant in stating a viable refusal to deal claim. *BroadCom*, 501 F.3d at 316. And *Host* indicates that a prior course of dealing is necessary in making out a Section 2 claim premised on a refusal to deal, as are facts suggesting "a willingness to forsake short-term profits to achieve an anticompetitive end." *Host Int'l*, 32 F.4th at 250 n.7. Other district courts in this Circuit have likewise found a history of dealing paired with facts suggesting a willingness to forsake short-term profits to be significant—and, in fact, necessary—in making out a viable Section 2 Sherman Act claim based on a refusal to deal. *See, e.g.*, *Blix Inc. v. Apple, Inc.*, No. 19-1869, 2020 WL 7027494, at *7 (D. Del. Nov. 30, 2020) (finding that

plaintiff's refusal to deal theory failed because plaintiff did not allege any facts "suggest[ing] [Apple's] willingness to forsake short-term profits to achieve an anticompetitive end" which could only be presumed from evidence of a "long-term business relationship"); *SEI Glob. Servs., Inc. v. SS&C Advent*, 496 F. Supp. 3d 883, 897 (E.D. Pa. 2020), *aff'd*, No. 20-3386, 2022 WL 2356730 (3d Cir. June 30, 2022) ("To proceed under *Aspen Skiing*'s narrow exception, SEI must show a preexisting voluntary *(and thus presumably profitable)* course of dealing with SS&C, and that the circumstances surrounding the termination of that relationship suggest[ ] a willingness to forsake short-term profits to achieve an anticompetitive end." (internal quotation and citation omitted)); *3Shape Trios A/S v. Align Tech., Inc.*, No. 18-1332, 2019 WL 3824209, at *7 (D. Del. Aug. 15, 2019), *report and recommendation adopted*, No. 18-1332, 2019 WL 4686614 (D. Del. Sept. 26, 2019) ("To proceed under the limited duty to deal exception created by *Aspen*, not only must the plaintiff show a pre-existing business relationship with the defendant, the circumstances surrounding the termination of that relationship must 'suggest[ ] a willingness to forsake short-term profits to achieve an anticompetitive end.'"); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 687 (E.D. Pa. 2014) (finding that the exception described in *Aspen Skiing* did not apply to impose liability on defendant that used a single shared REMS program as a means to undermine generic entry because there was no prior course of dealing between the parties, but distinguishing cases where REMS process was manipulated to completely preclude a generic from filing an ANDA). *But see IQVIA Inc. v Veeva Sys. Inc*., No. 17-0177, 2018 WL 4815547, at *3 (D.N.J. Oct. 3, 2018) (noting that "termination of a voluntary agreement and the willingness to forsake short-term profits are not necessary elements."); *Lannett Co., Inc. v. Celgene Corp.*, No. 08–3920 (E.D. Pa. Mar. 30, 2011) (D.E. No. 40) (denying motion to dismiss without comment even though plaintiff did not appear to plead a prior course of dealing);

Actelion Pharm. Ltd. v. Apotex, Inc., No. 12–5743 (D.N.J. Oct. 21, 2013) (D.E. No. 90) (denying motion for judgment on the pleadings "for reasons stated during oral argument" despite the fact that plaintiff did not appear to plead a prior course of dealing).

Further, as the Celgene Defendants point out (Mov. Br. at 45 n.16), a number of Circuit Courts, including the Second, Sixth, Eighth, Ninth, Tenth, Eleventh, and D.C. Circuits, have rejected the viability of a refusal to deal claim where there was no prior course of dealing. *See, e.g.*, *In Re Elevator Antitrust Litig.*, 502 F.3d 47, 53–54 (2d Cir. 2007) (finding that the unilateral-monopolization claims did not fall "within the sole exception to the right of refusal to deal" because "the complaint d[id] not allege that defendants terminated a prior relationship with elevator service providers," a change which could evince a willingness to forsake short-term profits to achieve an anticompetitive end)[44]; *see also In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134–35 (2d Cir. 2014), *as corrected* (June 19, 2014) ("Today, the sole exception to the broad right of a firm to refuse to deal with its competitors comes into play only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." (internal quotations and citation omitted)); *St. Luke's Hosp. v. ProMedica Health Sys., Inc.*, 8 F.4th 479, 486–87 (6th Cir. 2021) (finding that where "the monopolist [did not] enter a voluntary . . . course of dealing with its rival," the lack of a voluntary, prior course of dealing "signals that the antitrust laws do not apply");[45] *Park Irmat*

[44] To be sure, in *Mylan Pharms. v. Celgene Corp.*, No. 14-2094, 2014 WL 12810322, at *6 (D.N.J. Dec. 23, 2014), this Court noted that though *In Re Elevator* dismissed claims for failing to allege prior dealing, its focus was still on the willingness to forsake short-term profits for an anticompetitive end and did not address whether other factors could also indicate such a willingness. Nevertheless, the Second Circuit still emphasized that the case did not fall "within the *sole exception* to the right of refusal to deal" because "the complaint d[id] not allege that defendants terminated a prior relationship with elevator service providers," a change which could evince a willingness to forsake short-term profits to achieve an anticompetitive end. *In Re Elevator Antitrust Litig.*, 502 F.3d at 53–54 (emphasis added). And in *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134–35 (2d Cir. 2014) the Second Circuit reiterated that "[t]oday, the sole exception to the broad right of a firm to refuse to deal with its competitors comes into play only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134–35 (2d Cir. 2014), as corrected (June 19, 2014).

[45] The Insurer Plaintiffs and MSP Plaintiffs argue that the Sixth Circuit in *St. Luke's Hosp. v. ProMedica Health Sys.*, 8 F.4th 479 (6th Cir. 2021) did not establish a categorical rule that a prior course of dealing is necessary in

Drug Corp. v. Express Scripts Holding Co., 911 F.3d 505, 518 (8th Cir. 2018) (finding that *Aspen*'s limited exception was inapplicable because "Irmat and Express Scripts did not have a voluntary, years-long relationship regarding their competing mail-order pharmacies.");[46] *LiveUniverse, Inc. v. MySpace, Inc.*, 304 F. App'x 554, 556 (9th Cir. 2008) (stating that the refusal to deal exception "requires . . . the unilateral termination of a voluntary and profitable course of dealing.");[47] *FTC v. Qualcomm Inc.*, 969 F.3d 974, 993–95 (9th Cir. 2020) (noting that a company engages in prohibited anticompetitive conduct when (i) it "unilateral[ly] terminat[es] . . . a voluntary and profitable course of dealing;" (ii) "the only conceivable rationale or purpose is to sacrifice short-term benefits in order to obtain higher profits in the long run from the exclusion of competition;" and (iii) "the refusal to deal involves products that the defendant already sells in the existing market to other similarly situated customers" (internal quotations and citations omitted)); *Novell, Inc. v.*

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making a viable refusal to deal claim. (Opp. Br. at 46 n.174). In *St. Luke's Hosp.*, the Sixth Circuit noted that "a refusal to cooperate with rivals can constitute anticompetitive conduct and violate [Section] 2" under discrete circumstances. *St. Luke's Hosp.*, 8 F.4th at 486. The court found the following questions relevant to the inquiry. Did the monopolist enter a "voluntary . . . course of dealing" with its rival? *Id.* at 486–87 (citing *Trinko*, 540 U.S. at 409). Did the monopolist willingly sacrifice "short-run benefits . . . in exchange for a perceived long-run impact on its smaller rival"? *Id.* at 487 (citing *Aspen Skiing*, 472 U.S. at 611). And if so, did the monopolist ignore "efficiency concerns," or act without "valid business reasons"? *Id.* The Court found that answering "yes" to the above questions signals a potential Section 2 problem. *Id.* However, it expressly stated that answering "no" *to any of them* signals that the antitrust laws do not apply." *Id.* (emphasis added) (citations omitted). At oral argument, the Insurer Plaintiffs and MSP Plaintiffs contended that the Sixth Circuit's use of the word "signals" indicates that a lack of a prior course of dealing would not definitively doom the viability of a refusal to deal claim. (Tr. of Aug. 18, 2023 Oral Arg. at 63:20–63:2). The Court is not convinced. Contrary to the Insurer Plaintiffs and MSP Plaintiffs' assertions, the Sixth Circuit's statements on the issue indicate that a prior course of dealing is critical to the viability of a refusal to deal claim.

[46] In their Opposition Brief, the Insurer Plaintiffs and MSP Plaintiffs contend that in *Park Irmat Drug Corp. v. Express Scripts Holding Co.*, 911 F.3d 505, 518 (8th Cir. 2018), the Eighth Circuit never expressly stated whether a prior course of dealing is a precondition in imposing Section 2 liability, versus a factor that the court should consider in deciding whether to impose such liability. (Opp. Br. at 46 n.175). Nevertheless, at oral argument, the Insurer Plaintiffs and MSP Plaintiffs conceded that *Park Irmat* did in fact set down a categorical rule. (Tr. of Aug. 18, 2023 Oral Arg. at 67:8–12).

[47] The Insurer Plaintiffs and MSP Plaintiffs attempt to distinguish *LiveUniverse, Inc. v. MySpace, Inc.*, 304 F. App'x 554 (9th Cir. 2008) based on the fact that this case involved internet platforms that did not even sell products. (Opp. Br. at 46 n.175). However, in stating that the "narrow scope of the refusal to deal exception, [] requires, *inter alia*, the unilateral termination of a voluntary and profitable course of dealing," the Ninth Circuit made no indication that its statement should only be limited to the context of internet platforms. *LiveUniverse*, 304 F. App'x at 556. As such, the Insurer Plaintiffs' and MSP Plaintiffs' attempt to distinguish this case is unavailing.

Microsoft Corp., 731 F.3d 1064, 1074–75 (10th Cir. 2013) (Gorsuch, J.) (stating that "[t]o invoke *Aspen's* limited exception, the Supreme Court and we have explained, at least two features present in *Aspen* must be present in the case at hand" first, "as in *Aspen*, there *must* be a preexisting voluntary and presumably profitable course of dealing between the monopolist and rival" and second, "as in *Aspen*, the monopolist's discontinuation of the preexisting course of dealing must suggest[ ] a willingness to forsake short-term profits to achieve an anti-competitive end.") (emphasis added) (internal quotations omitted); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004) ("*Trinko* now effectively makes the unilateral termination of a voluntary course of dealing a requirement for a valid refusal-to-deal claim under *Aspen*."); *OJ Com., LLC v. KidKraft, Inc.*, 34 F.4th 1232, 1245 (11th Cir. 2022) (finding that the present case did not fit within the limited exception recognized in *Aspen Skiing* because "OJ Commerce ha[d] not established 'that [KidKraft] voluntarily engaged in a course of dealing with its rivals.'" (citation omitted)); *New York v. Meta Platforms, Inc.*, 66 F.4th 288, 305 (D.C. Cir. 2023) (stating that to fit within *Aspen*'s limited exception, a plaintiff must allege that, among other things, before the defendant refused its competitors access, the defendant "voluntarily engaged in a course of dealing with its rivals, or would . . . have done so absent statutory compulsion" and as such "Facebook's core functionality policy [] d[id] not fit *Aspen Skiing*'s exception to the extent it applied to apps with which Facebook had no prior course of dealing."). In addition, though the Seventh Circuit did not explicitly hold that a prior course of dealing was a necessary element of a refusal to deal claim, it allowed such a claim to proceed where the plaintiff's allegations included the "key element[]" of "prior course of voluntary conduct." *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 463 (7th Cir. 2020).

Based on the weight of authority in this area, the Court finds that the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot fall even "at or near the outer boundary of [Section] 2 liability" without alleging the unilateral termination of a voluntary and thus presumably profitable course of dealing, suggesting a willingness to forsake short-term profits to achieve an anti-competitive end. *Trinko*, 540 U.S. at 409. Because no such facts are alleged here, their Section 2 claim premised on a refusal to deal cannot proceed. To start, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene discontinued a preexisting voluntary and presumably profitable course of dealing with any of the generic competitors to which Celgene refused to provide samples of Revlimid or Thalomid. (*See, e.g.*, Humana Am. Compl. ¶¶ 116–226; MSP SAC ¶¶ 121–238). Nor have the Insurer Plaintiffs and MSP Plaintiffs alleged any facts suggesting that Celgene, in refusing to provide samples of Revlimid or Thalomid to generic competitors for bioequivalency testing, was forsaking short-term profits to achieve an anti-competitive end. As the Insurer Plaintiffs and MSP Plaintiffs allege, the generic competitors that requested samples of Revlimid or Thalomid from Celgene were doing so in order to conduct limited bioequivalency testing before filing an ANDA. (*See, e.g.*, Humana Am. Compl. ¶¶ 116–226; MSP SAC ¶¶ 121–238). The Court cannot draw the inference that Celgene was sacrificing any short-term profits merely by foregoing such limited sales, without any allegations indicating that those sales would have been profitable to Celgene. *See, e.g.*, *Blix*, 2020 WL 7027494, at *7 (finding that the plaintiff failed to state a plausible claim under Section 2 based on a refusal to deal because the plaintiff did not allege any facts suggesting that Apple earned profits by including the plaintiff's product in its MacOS App Store and thus was willing "to forsake short-term profits to achieve an anticompetitive end."). In fact, at oral argument, the Insurer Plaintiffs and MSP Plaintiffs conceded that Celgene's alleged conduct in refusing to provide samples of Revlimid or Thalomid to its generic competitors

did not suggest that Celgene was forsaking short-term profits. (Tr. of Aug. 18, 2023 Oral Arg. at 42:7–18 & 44:13–18). As such, because neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene discontinued a preexisting voluntary and presumably profitable course of dealing in refusing to provide generic competitors with samples of Revlimid or Thalomid, which suggested a willingness by Celgene to forsake short-term profits to achieve an anti-competitive end, the Court finds that their Section 2 claim cannot proceed insofar as it is premised on a refusal to deal.

The Court acknowledges that it reached a contrary conclusion in *Mylan Pharms. v. Celgene Corp.*, No. 14-2094, 2014 WL 12810322, at *4–6 (D.N.J. Dec. 23, 2014). There, Mylan similarly alleged that Celgene had violated Section 2 of the Sherman Act by refusing to sell it samples of Thalomid and Revlimid for bioequivalency testing. This Court allowed those similar allegations to proceed past Celgene's motion to dismiss and held that Mylan was not required to plead a prior course of dealing in order to state a Section 2 Sherman Act claim based on a refusal to deal. *Mylan*, 2014 WL 12810322, at *4–6. The Honorable Katharine S. Hayden, U.S.D.J. reached a similar conclusion in *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 9589217, at *15 (D.N.J. Oct. 29, 2015) (holding that the termination of a prior course of dealing between the defendant and a competitor was not a necessary element of a Section 2 refusal to deal claim). Nevertheless, since this Court issued its decision in *Mylan*, a number of additional Circuit Courts have rejected the viability of a refusal to deal claim under Section 2 of the Sherman Act where there was no prior course of dealing. *See St. Luke's Hosp.*, 8 F.4th at 486–87; *Park Irmat Drug Corp.*, 911 F.3d at 518; *see also OJ Com., LLC*, 34 F.4th at 1245; *Meta Platforms*, 66 F.4th at 306. Further, since the Court's decision in *Mylan*, the Third Circuit has at least noted—albeit only in dicta—that refusing to deal can sometimes establish an antitrust claim under Section 2, but "only among competitors, *and only if the parties have a history of dealing* paired with facts suggesting

'a willingness to forsake short-term profits to achieve an anticompetitive end.'" *Host Int'l, Inc.*, 32 F.4th at 250 n.7 (emphasis added). Accordingly, in light of the continued evolution of law in this area, this Court finds that, notwithstanding its prior holding in *Mylan*, the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot fall even at or near the outer boundary of Section 2 liability without alleging the unilateral termination of a voluntary and profitable course of dealing, suggesting a willingness to forsake short-term profits to achieve an anti-competitive end. As discussed above, because no such allegations are present here, their Section 2 claim premised on a refusal to deal cannot proceed.[48]

The Insurer Plaintiffs' and MSP Plaintiffs' remaining arguments to the contrary are unavailing. First, the Insurer Plaintiffs and MSP Plaintiffs rely on *Broadcom* in arguing that they need not allege a prior course of dealing to make out a viable Section 2 claim based on a refusal to deal. (Opp. Br. at 45). However, as the Celgene Defendants pointed out at oral argument, *Broadcom* is distinguishable. (Tr. of Aug. 18, 2023 Oral Arg. at 52:19–53:17). As described above, while the plaintiff in *Broadcom* did not allege a prior course of dealing between Qualcomm and its rivals, the Third Circuit noted in dicta that Qualcomm's voluntary participation in the standard setting process, and Qualcomm's voluntary commitment to license its technology on FRAND terms, constituted a voluntary course of conduct that distinguished the case from *Trinko*. *BroadCom*, 501 F.3d at 316. As such, by changing course and then licensing its technology on non-FRAND terms, Qualcomm altered a voluntary course of conduct, which appeared to be

[48] The Court notes that in *Mylan*, the Court's focus was still on what conduct could evidence a "willingness to forsake short-term profits for an anticompetitive end." *Mylan*, 2014 WL12810322, at * 4–6. Here, the Insurer Plaintiffs and MSP Plaintiffs conceded that Celgene's alleged conduct in refusing to provide samples of Revlimid or Thalomid to its generic competitors did not suggest that Celgene was forsaking short-term profits. (Tr. of Aug. 18, 2023 Oral Arg. at 42:7–18 & 44:13–18). Regardless, however, in light of the continued evolution of law in this area, this Court finds that, notwithstanding its prior holding in *Mylan*, the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot fall even at or near the outer boundary of Section 2 liability without alleging the unilateral termination of a voluntary and profitable course of dealing, suggesting a willingness to forsake short-term profits to achieve an anti-competitive end.

relevant as "evidence[ ] [of] the defendant's willingness to forego short-run profits for anticompetitive purposes." *Id*. In contrast, here, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene ever made a commitment to provide samples of Revlimid or Thalomid to its generic competitors and then altered that voluntary course of conduct in later refusing to sell samples of its drugs. As such, their reliance on *Broadcom* is unavailing.

Second, in arguing that they need not allege a prior course of dealing to make out a viable Section 2 claim based on a refusal to deal, the Insurer Plaintiffs and MSP Plaintiffs point out that there remains valid Supreme Court law imposing an affirmative duty to deal when no prior course of dealing was alleged, set forth in *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973). (Opp. Br. at 44). In fact, the Court acknowledges that it relied on *Otter Tail* in finding that Mylan was not required to plead a prior course of dealing in order to state a Section 2 Sherman Act claim based on a refusal to deal in *Mylan Pharms. v. Celgene Corp.*, No. 14-2094, 2014 WL 12810322, at *4–6 (D.N.J. Dec. 23, 2014). In *Otter Tail*, the Supreme Court found that the defendant—a vertically-integrated, highly-regulated utility company—used its monopoly in the retail distribution of electric power to inhibit local towns from shifting their services to municipal power providers. *Otter Tail*, 410 U.S. at 380. More specifically, in that case, Otter Tail sold electric power at retail to towns under short-term municipally granted franchises. Because each town could accommodate only one power distribution system, each town formed a natural monopoly for the retail sale of electric power. *Id.* at 368–69. After Otter Tail's franchise agreements expired, several municipalities voted to establish their own municipal retail distribution systems. *Id.* at 370–71. However, in an attempt to keep its former retail customers within the fold, Otter Tail refused to sell power at wholesale and refused to "wheel," or transfer, power to the municipal systems along its transmission lines, which were the only lines available, from other wholesalers to eliminate the

possibility of competition in the provision of retail electrical services. *Id.* at 369–71. The Supreme Court affirmed the district court's finding that Otter Tail had "used its monopoly power in the towns in its service area to foreclose competition or gain a competitive advantage, or to destroy a competitor, all in violation of the antitrust laws." *Id.* at 377. Notably, the Supreme Court found that Otter Tail violated Section 2 even when Otter Tail had not engaged in any prior dealings with its competitors, and the competitors—the municipal distribution systems—were only mere "potential entrants" into the market. *Id.* In *Trinko*, the Supreme Court cited favorably to *Otter Tail*, noting that Section 2 liability was imposed in *Otter Tail* because there the defendant was "in the business of providing a service to certain customers (power transmission over its network), and refused to provide the same service to certain other customers." *Trinko*, 540 U.S. at 410 (citing *Otter Tail*, 410 U.S. at 371, 377–78). This, the *Trinko* Court noted, was analogous to the situation in *Aspen Skiing*, where the defendant refused to sell a product to its competitor at retail price even though it had sold it at that price to other similarly situated customers. *Id.* at 409. As such, the Supreme Court in *Trinko* emphasized that in determining whether a plaintiff has adequately stated a Section 2 Sherman Act claim based on a refusal to deal, courts should examine whether the refusal to deal involves products that the defendant already sells in the existing market to other similarly situated customers. *Id.* at 409–10.

The Insurer Plaintiffs and MSP Plaintiffs contend that they need not allege a prior course of dealing to make out a viable Section 2 claim based on a refusal to deal because they argue that the present facts are analogous to the facts in *Otter Tail*, and there the Supreme Court found that Otter Tail violated Section 2 even when Otter Tail had not engaged in any prior dealings with its competitors. More specifically, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene refused to provide its generic competitors with samples of Revlimid or Thalomid for

bioequivalency testing because Celgene claimed that providing such samples would violate its REMS distribution program and pose safety concerns. (*See, e.g.*, Humana Am. Compl. ¶¶ 148, 206, 213, 218 & 224; MSP SAC ¶¶ 162, 221, 225, 230 & 234–36). Nevertheless, they allege that despite its practice of denying generic manufacturers access to Revlimid or Thalomid samples, Celgene authorized its competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required and provided several research organizations with access to Revlimid or Thalomid samples for the purpose of conducting clinical studies without raising the REMS program as a bar. (Humana Am. Compl. ¶¶ 227–34; MSP SAC ¶¶ 252–59). They argue that like in *Otter Tail*, Celgene provided samples of Revlimid or Thalomid to certain customers without raising the REMS program as a bar but refused to sell any samples to certain other customers—namely its generic competitors—even at retail prices, indicating that its refusals to deal were anticompetitive. (Opp. Br. at 43). As such, the Insurer Plaintiffs and MSP Plaintiffs contend that they need not allege a prior course of dealing to make out a viable Section 2 claim based on a refusal to deal because the Supreme Court found that Otter Tail violated Section 2 under similar circumstances even when Otter Tail had not engaged in any prior dealings with its competitors. Though the issue is close, the Court is now convinced by the Celgene Defendants' arguments, presented in their briefs and at oral argument, that the present facts are distinguishable from *Otter Tail*.

To start, as recounted above, in *Otter Tail*, the defendant refused to deal with competitors that were "potential entrants" into the market after its franchises with certain municipalities expired and those municipalities chose to displace Otter Tail with their own municipal distribution systems. *Otter Tail*, 410 U.S. at 368, 371. To be sure, Otter Tail did not have a prior course of dealing with its competitors—the municipal distribution systems—that were only mere "potential

entrants" into the market. However, it did formerly provide electric power at retail to customers in the municipalities in which those municipal distribution systems were established under short-term franchises. *Otter Tail*, 410 U.S. at 370–71 ("The antitrust charge against Otter Tail does not involve the lawfulness of its retail outlets, but only its methods of preventing the towns *it served* from establishing their own municipal systems when Otter Tail's *franchises expired*." (emphasis added)); *United States v. Otter Tail Power Co.*, 331 F. Supp. 54, 56, 58, 60–61 (D. Minn. 1971) ("From time to time citizens of some of the municipalities served by defendant have worked for the establishment of municipally owned electric facilities. Otter Tail has opposed such movements and has refused to sell power at wholesale, or to 'wheel' power, to its *former municipal customers* who have converted or who seek to convert to municipal systems." (emphasis added)). And in order to keep its former retail customers within the fold, Otter Tail refused to sell power to the municipal distribution systems at wholesale and refused to "wheel" power to those systems along its transmission lines solely to protect its monopolistic position. *Otter Tail*, 410 U.S. at 382 (Stewart, J., concurring in part and dissenting in part) (noting that Otter Tail refused to supply power to towns "which had formerly been its customers and had elected to establish municipally owned electric utility systems."). In other words, Otter Tail's conduct had the effect of disciplining its municipal customers—to which it had formerly provided retail power under municipally granted franchises—for attempting to erode its monopolistic position by displacing it with retail distribution systems of their own. *Id.* at 378. No such similar allegations are present here. More specifically, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene's conduct, in refusing to sell samples of Revlimid or Thalomid to generic competitors, had the effect of disciplining its former customers for attempting to erode its monopolistic position. (Tr. of Aug. 18, 2023 Oral Arg. at 47:17–48:11). *Otter Tail* is thus distinguishable in this respect. Further, as

a leading antitrust treatise has explained, *Otter Tail* seems to be restricted to its fairly limited set of facts. More specifically, it provides, "[t]he peculiarities of *Otter Tail* should be noted. First, the defendant possessed a natural monopoly. Second, this monopoly was partially regulated in ways that may have allowed it to operate to the detriment of consumers through vertical integration. Third, the case ought to be read in light of strong historical formulations from the common law imposing broad duties to deal on public utilities." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles & Their Application* ¶ 772b3 (5th ed. 2022); *see also id.* ¶ 778 (noting that *Otter Tail* is distinctive for two reasons that prevent its automatic application to other cases because it (i) involved a monopolist that was vertically integrated and thus "vertical integration into retail delivery might permit the utility to charge a monopoly retail price" even if an electric utility's wholesale price or wheeling charges might be effectively regulated by an appropriate agency; and (ii) was unique in its remedial aspects because the "Federal Power Commission already had the power to control some or all wholesale or wheeling charges under the then-existing federal regime, and the Court relied on that fact" as providing some mechanism for supervising and adjusting the price and other terms of dealing). Those particularities are not present in this case, further distinguishing *Otter Tail*. Accordingly, the Insurer Plaintiffs' and MSP Plaintiffs' reliance on *Otter Tail* is not sufficient to allow their Section 2 claim premised on a refusal to deal to proceed.

Third, in arguing that their Section 2 claim premised on a refusal to deal should proceed, the Insurer Plaintiffs and MSP Plaintiffs also argue that the present facts are analogous to the situation in *Aspen Skiing*, where the defendant refused to sell a product to its competitor at retail price even though it had sold it at that price to other similarly situated customers. They contend that similarly here, Celgene provided samples of Revlimid or Thalomid to certain customers

without raising the REMS program as a bar but refused to sell any samples to certain other customers—namely its generic competitors—even at retail prices, indicating that its refusals to deal were anticompetitive. (Humana Am. Compl. ¶¶ 227–34; MSP SAC ¶¶ 252–59). The Insurer Plaintiffs' and MSP Plaintiffs' attempt to analogize the present case to *Aspen Skiing* is similarly unavailing. To start, as already recounted above, this case is distinguishable from *Aspen Skiing* in large part because here neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene unilaterally terminated a voluntary and profitable course of dealing with any of the generic competitors with which Celgene later refused to deal—a distinction that is fatal to their Section 2 claim premised on a refusal to deal. However, it is also distinct from *Aspen Skiing* in another respect. As recounted above, in *Aspen Skiing*, the defendant, who owned three mountains in the Aspen Ski Area, and the plaintiff, who owned the fourth, had cooperated for years in the issuance of a joint, multiple-day, all-area ski ticket. *Aspen Skiing*, 472 U.S. at 591–92. "After repeatedly demanding an increased share of the proceeds, the defendant canceled the joint ticket." *Trinko*, 540 U.S. at 408 (citing *Aspen Skiing*, 472 U.S. at 593–94). And when Highlands attempted to purchase Aspen Skiing's lift tickets to create a multi-pass on its own for consumers, Aspen Skiing refused, even at retail price. *Aspen Skiing*, 472 U.S. at 593–94. As a result, consumers were adversely affected by the elimination, because over the years skiers had developed a strong demand for the 4-area ticket and many consumers felt that they could not go to the mountain of their choice once that pass had been eliminated. Accordingly, Aspen Skiing's refusal to deal cut off consumers from a product that they previously had access to before the change in distribution. In contrast, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that, by refusing to sell samples of Revlimid or Thalomid to generic competitors, Celgene cut off certain segments of its consumers

from products they previously had access to before Celgene's refusal. As such, *Aspen Skiing* is also distinguishable on this ground.

In sum, because neither the Insurer Plaintiffs' nor the MSP Plaintiffs' have alleged that Celgene unilaterally terminated a voluntary and profitable course of dealing in refusing to provide generic competitors with samples of Revlimid or Thalomid, suggesting a willingness by Celgene to forsake short-term profits to achieve an anti-competitive end, their Section 2 claim premised on a refusal to deal cannot proceed. And because the Supreme Court has cautioned that a Sherman Act violation for a refusal to deal "is at or near the outer boundary of [Section] 2," *Trinko,* 540 U.S. at 409, the Insurer Plaintiffs' and MSP Plaintiffs' reliance on *Otter Tail* and *Aspen Skiing*, which are distinct from this case in the aforementioned ways, is not sufficient to allow their Section 2 claim premised on a refusal to deal to proceed.

This case is also distinct from *Aspen Skiing* and *Otter Tail* in one other important manner, at least with respect to Celgene's refusals to sell samples of its drugs to certain generic competitors who had not obtained FDA approval of their study protocols before requesting such samples. "In *Aspen,* the Supreme Court found that Aspen Skiing[]'s conduct had *no* economic justification *except* [for] its tendency to exclude a rival." *Novell*, 731 F.3d at 1077 (citing *Aspen,* 472 U.S. at 608). Likewise, in *Otter Tail*, there existed no positive justification for the monopolist's actions, and indeed, Otter Tail did not contest that "its purpose in refusing to deal with municipalities desiring to establish municipally owned systems [wa]s to protect itself in the position it [] enjoy[ed] in the area." *Otter Tail*, 331 F. Supp. at 61. Here, however, the Celgene Defendants argue that Celgene had a legitimate business justification for refusing to provide samples of Revlimid to generic competitors before they had obtained FDA approval of their study protocols. (Mov. Br. at 49). And they point out that the Insurer Plaintiffs and MSP Plaintiffs have failed to allege that any

generic competitor, other than Mylan, had provided to Celgene proof of FDA approval of its study protocols for Revlimid before requesting samples. (*Id.*). As such, the Celgene Defendants argue that they cannot be subject to antitrust liability for refusing to deal with those generic competitors who had failed to obtain FDA approval of their study protocols before requesting samples of Revlimid. (*Id.*). The Court agrees. The court's decision in *Natco Pharma Ltd. v. Gilead Scis., Inc.*, No. 14-3247, 2015 WL 5718398, at *4–5 (D. Minn. Sept. 29, 2015) is instructive on this point. In *Natco*, the court dismissed a plaintiff's refusal to deal claim in part when a drug manufacturer cited a restricted distribution program as the reason for its refusal to sell the plaintiff drug samples for bioequivalency testing. *Natco*, 2015 WL 5718398, at *4–5. The court found that complying with FDA requirements constituted a valid business reason to refuse to dispense a drug outside of REMS requirements and as such found that the plaintiffs could not state a Section 2 claim based on a refusal to deal. *Id*. Further, as the Celgene Defendants point out, on summary judgment in the suit brought by Mylan against Celgene, this Court held that "until Celgene was informed about the FDA's approval of Mylan's testing protocols for either [Thalomid or Revlimid]—no reasonable jury c[ould] infer that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid or Revlimid." *Mylan Pharms. Inc. v. Celgene Corp.*, No. 14-2094, 2018 WL 11299447, at *15 (D.N.J. Oct. 3, 2018); (Mov. Br. at 49).

Likewise, here the Court agrees that on the face of the pleadings, Celgene had a legitimate business justification for refusing to provide certain generic competitors with samples of Thalomid or Revlimid before they had obtained FDA approval for their study protocols. As recounted above, Thalomid and Revlimid are highly dangerous drugs, and, accordingly, the FDA required that Celgene use certain precautions when distributing them. More specifically, to mitigate fetal exposure to Thalomid, the FDA conditioned its approval of Celgene's NDA for that drug on

Celgene's use of a REMS distribution program, known as S.T.E.P.S. (Humana Am. Compl. ¶¶ 100–01; MSP SAC ¶¶ 107–08). Likewise, in its letter to Celgene approving Revlimid, the FDA noted that the REMS distribution program for Revlimid, known as RevAssist, was "an important part of the post-marketing risk management" for the drug. (Humana Am. Compl. ¶ 104; MSP SAC ¶ 113). Accordingly, "[b]oth Revlimid and Thalomid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the RevAssist or S.T.E.P.S. programs, respectively, and patients to be enrolled in these programs, before prescribing, dispensing, or taking the drugs, respectively." (Humana Am. Compl. ¶ 112; *see also* MSP SAC ¶ 116). As the Insurer Plaintiffs and MSP Plaintiffs allege, when generic competitors began requesting samples of Revlimid or Thalomid for bioequivalency testing, Celgene declined to provide such samples, asserting that providing such samples would violate its REMS distribution programs, which were required by the FDA, and pose safety concerns. (*See, e.g.*, Humana Am. Compl. ¶¶ 148–50, 209, 213–14, 218 & 224; MSP SAC ¶¶ 162, 188–93, 195–200, 221, 225–26, 230 & 234–36). In fact, at least with respect to Thalomid, the Insurer Plaintiffs and MSP Plaintiffs allege that after certain generic manufacturers reached out to the FDA to obtain assistance in procuring samples from Celgene, the FDA provided that "certain restrictions [we]re needed to ensure safe use of the drug" and stated that Celgene could provide samples when it received "confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects." (*See, e.g.*, Humana Am. Compl. ¶¶ 136 & 183; MSP SAC ¶¶ 143 & 198). These allegations support the legitimacy of Celgene's concerns around the safe distribution of its drugs. Accordingly, unlike in *Aspen Skiing* and *Otter Tail*, where the defendants had no positive

justifications for their refusal to deal, here the Insurer Plaintiffs' and MSP Plaintiffs' allegations indicate that Celgene had a "valid business reason" to refuse to provide Revlimid or Thalomid outside of REMS requirements and without FDA approval. This further distinguishes the present facts from *Aspen Skiing* and *Otter Tail* and supports the dismissal of the Insurer Plaintiffs' and MSP Plaintiffs' Section 2 claim premised on a refusal to deal, at least with respect to Celgene's refusals to sell samples to generic competitors who had not received FDA approval of their protocols. *See Natco Pharma*, 2015 WL 5718398, at *4–6 (granting motion to dismiss Section 2 refusal-to-deal claims, in part, because "complying with FDA requirements requiring a valid prescription before dispensing [the brand product] constitutes a valid business reason to refuse to dispense [the brand product] outside of the REMS requirements"); *Simon & Simon, PC v. Align Tech., Inc.*, No. 19-0506, 2019 WL 5191068, at *6 (D. Del. Oct. 15, 2019) (finding that plaintiff failed to plead Section 2 claim premised on refusal to deal where complaint itself revealed a procompetitive explanation for the refusal to deal and "there is no allegation (plausible or otherwise) that [defendant's] conduct made no economic sense").

To be sure, the Insurer Plaintiffs and MSP Plaintiffs do allege that some generic competitors did obtain FDA approval of their distribution programs prior to requesting samples of Revlimid or Thalomid. More specifically, the Insurer Plaintiffs and MSP Plaintiffs do allege that Celgene continued to refuse to provide Mylan with samples of Revlimid even after it received FDA approval of its study protocols. (Humana Am. Compl. ¶¶ 153–54; MSP SAC ¶¶ 159–60). And the MSP Plaintiffs allege that Celgene continued to refuse to provide Mylan, Lannett, and Exela with samples of Thalomid even after they received FDA approval of their study protocols. (MSP SAC ¶¶ 144–46, 190–93, 196–200). However, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that *all* of the generic competitors obtained FDA approval of their distribution

programs prior to requesting samples of Revlimid or Thalomid. More specifically, they do not allege that Dr. Reddy's, Watson, Teva, or Sandoz received any such approval before requesting samples of Revlimid, but rather allege only that those competitors provided Celgene assurances that its testing would comply with FDA guidelines. (Humana Am. Compl. ¶¶ 207, 212, 217 & 224; MSP SAC ¶¶ 219, 224, 229 & 236). And the MSP Plaintiffs do not allege that Watson or Sandoz received any FDA approval of their protocols before requesting samples of Thalomid. (MSP SAC ¶¶ 229 & 236).[49] As discussed above, the entirety of the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot proceed as pled because neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene unilaterally terminated a voluntary and profitable course of dealing with any of the generic competitors with which it later refused to deal, suggesting a willingness by Celgene to forsake short-term profits to achieve an anti-competitive end. Nevertheless, in addition, because Celgene had a "valid business reason" to refuse to provide Revlimid or Thalomid outside of REMS requirements and without FDA approval, the Court further finds that the Insurer Plaintiffs' and MSP Plaintiffs' Section 2 claim premised on a refusal to deal cannot proceed at least with respect to Celgene's refusals to sell samples to generic competitors who had not received FDA approval of their protocols, including Dr. Reddy's, Watson, Teva, and Sandoz. *See Natco Pharma*, 2015 WL 5718398, at *4–6.[50]

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[49] While the Insurer Plaintiffs and MSP Plaintiffs also alleged that Sandoz received FDA approval to purchase samples of Celgene's drugs, following oral argument, the Insurer Plaintiffs and MSP Plaintiffs withdrew those allegations. (*In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action No. 19-7532 (D.E. No. 229); *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 223)).

[50] The Insurer Plaintiffs appear to contend that Celgene did not have a valid business reason to refuse to provide samples of its drugs because refusing to provide such samples was company policy for all generics, regardless of FDA approval. (Opp. Br. at 48 n.185). The Court is not convinced. As the Celgene Defendants point out, in the suit brought by Mylan against Celgene, this Court held that "until Celgene was informed about the FDA's approval of Mylan's testing protocols for either [Thalomid or Revlimid]—no reasonable jury c[ould] infer that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid or Revlimid." *Mylan*, 2018 WL 11299447, at *15. The same is true here. More specifically, until Celgene was informed about the FDA's approval of its competitors' testing protocols for either Thalomid or Revlimid, the Court cannot plausibly infer that

Finally, the Supreme Court in *Trinko* made clear that the "regulatory context . . . may also be a consideration in deciding whether to recognize an expansion of the contours of [Section] 2." *Trinko*, 540 U.S. at 412. In fact, *Trinko* emphasized that any such regulatory structure diminishes the need for antitrust scrutiny. *Id.* at 412. Here, the Insurer Plaintiffs and MSP Plaintiffs point out that Congress included a provision in the FDA Amendments Act that explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. (Humana Am. Compl. ¶¶ 64 & 115; MSP SAC ¶¶ 72 & 120). That provision provides in relevant part the following: "No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an . . . [ANDA]." 21 U.S.C. § 355-1(f)(8).[51] As such, the Insurer Plaintiffs and MSP Plaintiffs contend that Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to this provision. (Humana Am. Compl. ¶¶ 64 & 115; MSP SAC ¶¶ 72 & 120). To the extent that § 355–

Celgene had no objectively legitimate business justification for not selling its drugs to those competitors. *See Natco Pharma*, 2015 WL 5718398, at *4–6; *Simon & Simon, PC*, 2019 WL 5191068, at *6.

[51] In fact, based on this provision, the Insurer Plaintiffs and MSP Plaintiffs contend that applying a prior course of dealing requirement would allow drug manufacturers to "nullify" Hatch Waxman, because the Hatch-Waxman Act was enacted to promote generic competition and expressly forbade branded drug makers from abusing REMS to "block or delay" generic competition. (Opp. Br. at 47–48 (citing 21 U.S.C. § 355-1(f)(8)). This argument does not lead the Court to reach a contrary conclusion. To start, as the Celgene Defendants point out (Reply at 24), though 21 U.S.C. § 355-1(f)(8) provides that drug makers shall not use REMS to "block or delay" the approval of an ANDA, it does not appear to obligate drug makers to provide samples of their products to generics on demand. 21 U.S.C. § 355-1(f)(8). As such, while a prior course of dealing requirement might prevent courts from imposing liability on brand manufacturers based on their refusals to provide generic competitors with samples of their drug, that outcome does not necessarily run counter to § 355-1(f)(8). Further, as the Insurer Plaintiffs allege, in December 20, 2019, Congress enacted material portions of the "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" (commonly known as "CREATES") to combat REMS abuse, which obligates the sale of REMS-governed products for testing by generics and establishes a stand-alone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms." (Humana Am. Compl. ¶ 66 (citing 21 U.S.C. § 355-2(b)). Accordingly, based on the Insurer Plaintiffs own allegations, adopting a prior course of dealing requirement here does not leave generic competitors without recourse. Finally, it is worth noting that "to the extent that *Aspen's* test still might be accused of being underinclusive to some degree even in the narrow field of refusals to deal, the general rule is firm independence and refusal to deal doctrine exists only to address one of the most obvious exceptions to that general rule. If the doctrine fails to capture every nuance, if it must err still to some slight degree, perhaps it is better that it should err on the side of firm independence—given its demonstrated value to the competitive process and consumer welfare—than on the other side where [courts] face the risk of inducing collusion and inviting judicial central planning." *Novell*, 731 F.3d at 1076.

1(f)(8) prohibits brand name drug manufacturers from manipulating the REMS process to cause delay, this statute provides for increased FDA oversight and diminishes the need for antitrust scrutiny. *See, e.g.*, *In re Suboxone*, 64 F. Supp. 3d at 687 ("Plaintiffs rely heavily upon 21 U.S.C. § 355–1(f)(8), which requires the parties to work together in good faith and not use the SSRS process to block or delay ANDA approval. However, . . . [a] regulatory structure requiring cooperation actually diminishes the need for antitrust scrutiny."). In fact, as the Insurer Plaintiffs and MSP Plaintiffs allege, after certain generic manufacturers reached out to the FDA to obtain assistance in procuring samples from Celgene, the FDA set up a process by which it would review study protocols from Celgene's generic competitors to ensure that they were safe. (*See, e.g.*, Humana Am. Compl. ¶ 157 (stating that the FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols); MSP SAC ¶¶ 144–45, 163, 191 & 202 (stating that the FDA notified Celgene that it accepted Mylan's submitted thalidomide and lenalidomide safety protocols and authorized Exela and Lannett to obtain Thalomid samples); (Tr. of Aug. 18, 2023 Oral Arg. at 38:21–39:1)). Though, as the Celgene Defendants admit (Reply at 24), § 355–1(f)(8) does not appear to give the FDA the power to compel Celgene to turn over samples of their drug products to generic manufacturers, the FDA's involvement in this process suggests that the need for antitrust scrutiny may be diminished in this context. *Trinko*, 540 U.S. at 412.[52]

[52] The Court notes that the diminished need for antitrust scrutiny in this area seems more apparent now, given that, as the Insurer Plaintiffs and MSP Plaintiffs point out, on December 20, 2019, Congress enacted CREATES to combat REMS abuse, which obligates the sale of REMS-governed products for testing by generics and establishes a stand-alone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms." (Humana Am. Compl. ¶ 66 (citing 21 U.S.C. § 355-2(b)). While this provision was not in place at the time that Celgene was allegedly refusing to provide samples to its generic competitors and does not appear to provide a remedy for past REMS abuse, the Insurer Plaintiffs themselves admit that it now "establishes a prospective counterbalance to monopolistic schemes." (*Id.* ¶ 67). At oral argument, the Insurer Plaintiffs and MSP Plaintiffs contended that this provision does not diminish the need for antitrust scrutiny, even now, because the statute includes a savings clause that provides "[n]othing in the section shall be construed to limit the operation of any provisions of the antitrust law." (Tr. of Aug. 18, 2023 Oral Arg. at 41:2–11 (citing 21 U.S.C. § 355-2(e)(2)). However, the mere fact that CREATES may not shield regulated entities from antitrust scrutiny altogether does not mean that it does not *diminish* the need for antitrust scrutiny. In fact, the Supreme Court in *Trinko* grappled with a similar issue.

In sum, in light of (i) the Supreme Court's emphasis that a Sherman Act violation for a refusal to deal "is at or near the outer boundary of [Section] 2 liability," *Trinko*, 540 U.S. at 409; (ii) the Third Circuit's suggestion in *Broadcom* that an alteration in a voluntary course of conduct is significant in stating a viable refusal to deal claim, *BroadCom*, 501 F.3d at 316, and the Third Circuit's indication in *Host* that a prior course of dealing is necessary in making out a Section 2 claim premised on a refusal to deal, as are facts suggesting "a willingness to forsake short-term profits to achieve an anticompetitive end," *Host Int'l*, 32 F.4th at 250 n.7; and (iii) the numerous other Circuit Court decisions that have rejected the viability of a refusal to deal claim where there was no prior course of dealing, the Court finds that the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations cannot proceed, as they have not alleged that Celgene discontinued a preexisting voluntary and presumably profitable course of dealing in refusing to provide generic competitors with samples of Revlimid or Thalomid that suggested a willingness by Celgene to forsake short-term profits to achieve an anti-competitive end. *Trinko*, 540 U.S. at 409. Further, as described above, the Insurer Plaintiffs' and MSP Plaintiffs' reliance on *Otter Tail* is not sufficient to allow their Section 2 claim premised on a refusal to deal to proceed. As such, the Court declines to expand the bounds of Section 2 liability to accommodate the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations. *Novell*, 731 F.3d at 1076 ("If the [refusal to deal] doctrine fails to capture every nuance, if it must err still to some slight degree, perhaps it is better that it should err on the side of firm independence—given its demonstrated value to the competitive process and consumer welfare—than on the other side where we face the risk of inducing collusion and inviting judicial central planning."). In addition, because based on the face of the pleadings

More specifically, in *Trinko*, even though the Telecommunications Act of 1996 in that case included a savings clause which precluded the Supreme Court from ruling that the regulated entities were "shielded from antitrust liability altogether" the Supreme Court nevertheless found that the regulations in place diminished the need for antitrust scrutiny in that instance. *Trinko*, 540 U.S. at 406–07.

Celgene had a "valid business reason" to refuse to provide Revlimid or Thalomid outside of REMS requirements and without FDA approval, the Court further finds that the Insurer Plaintiffs' and MSP Plaintiffs' Section 2 claim premised on a refusal to deal cannot proceed at least with respect to Celgene's refusals to sell samples to generic competitors who had not received FDA approval of their protocols, including Dr. Reddy's, Watson, Teva, and Sandoz. *See Natco Pharma*, 2015 WL 5718398, at *4–6. Accordingly, insofar as the Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by refusing to sell samples of Revlimid to generic manufacturers for bioequivalency testing, this component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act based on a refusal to deal.[53] The Court reaches the same conclusion with respect to the MSP Plaintiffs' refusal to deal allegations related to Thalomid.

iii. The Reverse Payment Allegations and Market Allocation Theory

The Insurer Plaintiffs next allege that the Celgene Defendants violated Section 1 and Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with generic competitor, Natco. The Insurer Plaintiffs also allege that, separate and apart from their reverse payment theory, the settlement agreement between Celgene and Natco amounted to an unlawful market allocation agreement. The MSP Plaintiffs also allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into anticompetitive reverse payment settlement agreements with multiple other generic competitors. Because the Insurer Plaintiffs' and MSP Plaintiffs' reverse payment allegations are distinct, the Court will analyze the sufficiency of their allegations in turn. For the reasons set forth below, the Court finds that neither

[53] Because the Court grants the Celgene Defendants' motion on the aforementioned grounds, it does not consider its additional arguments in support of dismissing the Insurer Plaintiffs' and MSP Plaintiffs' refusal to deal allegations. (Mov. Br. at 50).

the Insurer Plaintiffs nor the MSP Plaintiffs have plausibly pleaded a reverse payment between Celgene and any of its generic competitors. Further the Court finds that the Insurer Plaintiffs have failed to plausibly allege that the settlement agreement between Celgene and Natco amounted to an unlawful market allocation.

a. The Insurer Plaintiffs' Reverse Payment Allegations

"Often arising from pharmaceutical drug litigation, reverse payment settlement agreements operate counter to conventional settlement norms." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017). "As traditionally understood, settlements involve an agreement by a defendant (i.e., a patent infringer in the pharmaceutical drug context) to pay a plaintiff (i.e., the patentee) to end a lawsuit." *Id.* at 249–50. "A reverse payment settlement agreement instead 'requires the patentee to pay the alleged infringer,' in return for the infringer's agreement not to produce the patented item. *Id.* (citing *Actavis*, 570 U.S. at 140–41).

In *FTC v. Actavis*, 570 U.S. 136 (2013), the Supreme Court held that reverse payments "can sometimes unreasonably diminish competition in violation of the antitrust laws." *Actavis*, 570 U.S. at 141. In that case, Solvay sued Actavis, Inc., a company seeking to market a generic version of AndroGel. *See id.* at 145. Solvay and Actavis ultimately settled pursuant to the following terms: (i) "Actavis agreed that it would not bring its generic to market until . . . 65 months before Solvay's patent expired (unless someone else marketed a generic sooner)"; (ii) "Actavis also agreed to promote AndroGel to urologists"; and (iii) "Solvay agreed to pay . . . an estimated $19–$30 million annually, for nine years, to Actavis." *Id.* The FTC sued Solvay and Actavis, contending that the payments compensated Actavis for delaying its market entry. *See id.* The district court dismissed the FTC's complaint, and the United States Court of Appeals for the Eleventh Circuit affirmed. *See id.* at 145–46. In doing so, both courts applied the "scope of the

patent" test, which provides that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 146. This "categorical rule . . . relied on the premise that, because a patentee possesses a lawful right to keep others out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market." *Lipitor*, 868 F.3d at 250 (citing *Actavis*, 570 U.S. at 146).

The Supreme Court rejected that approach and reversed the Eleventh Circuit. It found that the Eleventh Circuit had erred in analyzing the plaintiff's antitrust claim only with reference to patent law policies. The Supreme the Court explained that "[i]t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, and not against procompetitive antitrust policies as well." *Actavis*, 540 U.S. at 148. Instead, it stated that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* Hence, the Supreme Court found that patent-related "reverse payment settlements . . . can sometimes violate the antitrust laws[.]" *King Drug*, 791 F.3d at 399 (quoting *Actavis*, 570 U.S. at 149).

The Supreme Court based its conclusion on five principal considerations. First, it noted that "reverse payments can be anticompetitive because they allow a brand-name company to split its monopoly profits with a generic company willing to delay market entry." *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 352 (3d Cir. 2020) (citing *Actavis*, 570 U.S. at 153–56). Second, it recognized that reverse payments' "anticompetitive consequences will at least sometimes prove unjustified." *Actavis*, 570 U.S. at 156. On the one hand, a defendant might show that "traditional settlement considerations, such as avoided litigation costs or fair value for services" justified the

reverse payment. *Id.* Conversely, antitrust scrutiny could reveal "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement," in which case the payment is not justified. *Id.* Third and fourth, it explained that "the 'size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness' and a patentee's market power, 'all without forcing a court to conduct a detailed exploration of the patent itself.'" *AbbVie Inc*, 976 F.3d at 352 (citing *Actavis*, 570 U.S. at 157–58) (alteration in original) citation omitted). Fifth, the Supreme Court made clear that subjecting reverse payments to antitrust review does not violate the general legal policy in favor of settlements, because a patentee and purported infringer may still lawfully settle their suit by other means. *Actavis*, 570 U.S. at 158. It observed, for instance, that they may settle by "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* Ultimately, the Court concluded, "a reverse payment, where *large and unjustified*," can violate the antitrust laws. *Id.* at 158–60 (emphasis added).

Since the Supreme Court decided *Actavis*, the Third Circuit has applied its teachings on a motion to dismiss on three main occasions. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017); *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327 (3d Cir. 2020).

In *King Drug*, the Third Circuit reinstated a complaint challenging a settlement agreement in which the alleged reverse payment took a form other than cash. *See King Drug*, 791 F.3d at 393. There, the allegedly unlawful reverse payment took the form of a "no-AG agreement," a brand-name manufacturer's promise not to produce an authorized generic to compete with the generic manufacturer. *Id.* at 397. The Third Circuit held that a reverse payment underlying an *Actavis* antitrust claim need not be in cash form. *Id.* at 403–09. The court explained that even

though the brand manufacturer, GSK, did not pay the generic manufacturer, Teva, cash under the agreement, the agreement was "likely to present the same types of problems as reverse payments of cash" because the no-AG agreement could have been worth millions of dollars, if not hundreds of millions of dollars, to Teva. *Id.* at 404. Conversely, GSK's commitment not to produce an authorized generic transferred to Teva "the profits [GSK] would have made from its authorized generic." *Id.* at 405. As such, the Third Circuit held that the plaintiffs had stated a claim, reasoning that the agreement may have been "something more than just an agreed-upon early entry"—it may have been "pay-for-delay." *Id.* Because the complaint in *King Drug* plausibly alleged a large and unjustified reverse payment, the Third Circuit found that the plaintiffs there could proceed to prove their claim through discovery under "the traditional rule-of-reason approach."[54] *Id.* at 411.

In *Lipitor*, the Third Circuit addressed consolidated appeals concerning two drugs: Lipitor and Effexor XR. *See Lipitor*, 868 F.3d at 239. In the Lipitor litigation, the plaintiffs sued Lipitor's brand-name producer (Pfizer Inc.) and its generic applicant (Ranbaxy Inc.) over a "near-global" litigation settlement addressing "scores of patent litigations [between Pfizer and Ranbaxy] around the world." *Id.* at 244. One part of the settlement provided that Ranbaxy would delay its entry, "thus extending Pfizer's exclusivity in the Lipitor market" past the expiration of Pfizer's patents. *Id.* at 244–45. Another part of the settlement resolved Pfizer's claim against Ranbaxy for allegedly

[54] Under the "rule of reason" burden-shifting framework, the party seeking to impose liability must initially provide evidence of the anticompetitive nature of a defendant's conduct. *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 438 (3d Cir. 2016). Once established, the defendant then has the burden of proffering nonpretextual procompetitive justifications that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal. *See id.*; *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, No. 16-5073, 2017 WL 4642285, at *8 (E.D. Pa. Oct. 17, 2017). And "[t]he plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Mylan Pharm.*, 838 F.3d at 438 (alteration in original) (internal quotation marks omitted). The *Actavis* Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. *King Drug*, 791 F.3d at 412. First, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. *Actavis*, 570 U.S. at 154–56. Second, the burden then shifts to the defendant to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 156. Finally, the plaintiff will have the opportunity to rebut the defendant's explanation. *King Drug*, 791 F.3d at 412.

infringing Pfizer's patents on Accupril, a different drug. *Id.* at 243–44. Before settling, Pfizer had reason to believe its Accupril claim was worth hundreds of millions of dollars. *Id.* Nevertheless, Pfizer agreed to settle this claim for just $1 million. *See id.* at 244. Reversing the district court, the Third Circuit held that these two otherwise-unrelated parts of the global settlement agreement were actionable under *Actavis*. *See id.* at 248, 253. First, the Third Circuit rejected the requirement, imposed by the district court, that the plaintiffs plead a "reliable" monetary estimate of the dropped Accupril claims, explaining that it "heightened [the] pleading standard contrary to *Bell Atlantic v. Twombly*, [550 U.S. 544, (2007)], and *Ashcroft v. Iqbal*, [556 U.S. 662 (2009)]." *Id.* at 254. Second, the Third Circuit rejected the defendants' argument that the plaintiffs did not address other parts of the global litigation settlement that might well have justified the alleged reverse payment. The Third Circuit held that *Actavis* did not "require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations." *Id.* at 256. Third, the defendants argued that because Ranbaxy paid Pfizer $1 million to settle the Accupril suit, it was a commonplace settlement to which *Actavis* did not apply. *Id.* at 257. The Third Circuit stated that this argument "[could not] be squared with *Actavis*" because "[i]f parties could shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to eliminate the risk of competition would escape review." *Id.* at 258.

In the Effexor XR litigation, plaintiffs sued Effexor's generic applicant (Teva) and brand-name producer (Wyeth, Inc.) over their settlement of Teva's challenge to the validity and enforceability of Wyeth's patents on Effexor. *See id.* at 247. Under the settlement, the parties agreed that Teva could market the extended-release version of its generic nearly seven years before Wyeth's patent expired, and its instant-release version at some point before the patent expired. *See*

id. In exchange, Wyeth agreed it would not market authorized generics during Teva's 180-day exclusivity period (a no-AG agreement). *See id.* Teva, in turn, agreed to pay Wyeth royalties. *See id.* The Third Circuit held that the no-AG agreement was actionable under *Actavis*. *Id.* at 260–61. Though the defendants argued that the royalties Teva agreed to pay Wyeth justified the reverse payment, the court found that an analysis of the royalty licensing provisions "require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage." *Id.* at 261.

Finally, in *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327 (3d Cir. 2020), the Third Circuit found that the FTC plausibly alleged an anticompetitive reverse payment between generic applicant (Teva) and brand name producer (AbbVie) regarding AndroGel. Under the agreement, Teva agreed to "drop its patent challenge and refrain from competing with [AndroGel] until December 2014," six years before the relevant patent expired. *Id.* at 343, 357 (alteration in original). In exchange, AbbVie agreed to grant Teva a license to sell a generic version of an unrelated drug called TriCor, which AbbVie would supply to Teva at Teva's option, for a four-year term beginning in November 2012. *Id.* at 357. "This supply agreement provided for Teva to pay AbbVie the costs of production, an additional percentage of that cost, and a royalty." *Id.* In finding that these allegations plausibly alleged an anticompetitive reverse payment, the Third Circuit first found that the payment was plausibly large. The FTC alleged that the supply of TriCor was "extremely valuable" to Teva. *Id.* More specifically, Teva expected its "net sales of authorized generic TriCor sales would be nearly $175 million over a four-year period." *Id.* (internal quotation marks omitted). And this far exceeded the litigation costs that AbbVie or Teva saved by settling. *Id.* Further, the Third Circuit found that the payment was also plausibly "unjustified." *Id.* The FTC alleged that the TriCor deal could not be explained as an independent

business deal from AbbVie's perspective because AbbVie "had no incentive to increase . . . generic competition from Teva on another of its blockbuster products." *Id.* (internal quotation marks omitted). And while the District Court had emphasized that Teva paid AbbVie for the supply of TriCor, the Third Circuit again noted that parties cannot "shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer." *Id.* at 359 (internal quotation marks omitted).

In *AbbVie*, the Third Circuit explained that two principles emerged from the Supreme Court's decision in *Actavis* and Third Circuit law interpreting that decision. *First*, the Third Circuit stated that "a reverse payment's legality depends mainly on its economic substance, not its form." *Id.* at 356. "The alleged reverse payment in *Actavis* was made in cash. Yet the alleged reverse payments in *King Drug* and *Lipitor* included two no-AG agreements and the settlement of a valuable damages claim," and the alleged reverse payment in *AbbVie* included a lucrative supply agreement on an unrelated drug. *Id.* The Third Circuit noted that, however meaningful it may be in other areas of the law to have a formulaic rule for determining whether an agreement is or is not violative of the law, such rules are disfavored in antitrust. *Id.* The purpose of antitrust law is "to protect consumers from arrangements that prevent competition in the marketplace." *King Drug*, 791 F.3d at 406 (citations omitted). Because of that unique purpose, the Third Circuit emphasized that "economic realities rather than a formalistic approach must govern." *AbbVie Inc.*, 976 F.3d at 356 (quoting *United States v. Dentsply, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005)). Accordingly, in *AbbVie*, *King Drug* and *Lipitor*, the Third Circuit read *Actavis* practically; it read it to apply to potentially anticompetitive reverse payments regardless of their form. *Id.*

Second, the Third Circuit emphasized that the law of pleading applies to reverse-payment theories. Pursuant to *Actavis*, to trigger antitrust concerns, the settlement term at issue must be (i)

a "payment" that is (ii) made in "reverse," namely, from the patent holder to the alleged infringer and is (iii) "large," and (iv) "unexplained." *Actavis*, 570 U.S. at 156–58; *see also Sergeants Benevolent Ass'n Health & Welfare Fund v. Acta Vis, PLC*, No. 15-6549, 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (quoting *In re Actos End Payor Antitrust Litig.*, No. 13-9244, 2015 WL 5610752, at *11 (S.D.N.Y. Sept. 22, 2015)). In *Actavis*, though the Court did not define what constitutes a large or unjustified reverse payment, it did provide some guidance. To start, it instructed courts to compare a payment to the payor's future litigation costs as a measure of scale to determine if the payment was "large." *Actavis*, 570 U.S. at 159. Further, it instructed courts to consider whether a payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services" to determine if it was justified. *Id.* at 156. As the Third Circuit explained in *Lipitor*, an antitrust plaintiff need only allege the absence of a "convincing justification" for the payment. *Lipitor*, 868 F.3d at 256. The Third Circuit noted that "[a] plaintiff can meet this pleading standard without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it." *AbbVie*, 976 F.3d at 356. Rather, a district court must accept a plaintiff's well-pleaded allegations as true. *Id.* "If a plaintiff plausibly alleges that an agreement's anticompetitive effects outweigh its procompetitive virtues, the district court must accept that allegation and allow the plaintiff to take discovery." *Id.* "If genuine issues of material fact remain, the rule-of-reason analysis is for the factfinder, not the court." *Id.*

Nevertheless, notwithstanding *Actavis*'s prohibition on large, unjustified reverse payments, the Supreme Court made clear that a patentee and purported infringer may still lawfully settle their suit by other means. It observed, for instance, that they may settle "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee

paying the challenger to stay out prior to that point." *Actavis*, 570 U.S. at 158. Because the "existence and degree of any anticompetitive" effects may vary depending on the settlement and the relevant industry, reverse payments are not presumptively unlawful. *Id.* at 159.

The Insurer Plaintiffs allege that the settlement agreement between Celgene and Natco comprised a two-pronged in-kind payment: (i) a volume limited, royalty-free generic license before full generic competition began, amounting to hundreds of millions of dollars in payment to Natco; and (ii) an acceleration or most-favored entry ("MFE") clause that both deterred later-filing generics from challenging Celgene's patents through judgment and induced Natco to accept a later entry date by eliminating the risk that Natco loses its lucrative exclusivity period. (Humana Am. Compl. ¶ 341). For the reasons set forth below, the Court finds that neither the (i) volume limited, royalty free license nor (ii) the MFE clause plausibly amount to a "payment" that is made in "reverse," namely, from Celgene to Natco, under *Actavis*.

Volume Limited Royalty-Free License. The Insurer Plaintiffs allege that the settlement agreement between Celgene and Natco constituted an unlawful reverse payment because it provided Natco with a "volume limited, royalty-free generic license before full generic competition began equating to hundreds of millions of dollars in payment to Natco." (Humana Am. Compl. ¶ 341). According to the Insurer Plaintiffs, this volume-limited, royalty-free license gave Natco no incentive to compete on price and ensured that Natco's capped level sales could not effectuate bona fide downward generic price pressure, keeping prices for both Revlimid and generic lenalidomide at supracompetitive levels. (*Id.* ¶¶ 419–31). Further, because Celgene's brand Revlimid could retain whatever share of the market Celgene did not allocate to Natco, the Insurer Plaintiffs allege that the volume-limited, royalty free license disincentivized Celgene from launching its own authorized generic. (*Id.* ¶¶ 441–43). The Insurer Plaintiffs allege that this

functional no-AG promise constituted a reverse payment because Celgene transferred the profits it would have made from its AG to Natco and assured Natco that it would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise would were it competing with an AG. (Humana Am. Compl. ¶¶ 437–38, 441–43). As such, the Insurer Plaintiffs allege that the volume-limited, royalty free license constituted a reverse payment because, under the agreement, Natco would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise would and the absence of any royalties meant that Natco would make hundreds of millions of dollars more than it would have even if it had won the patent dispute and launched into a competitive marketplace. (Opp. Br. at 18; Humana Am. Compl. ¶¶ 418–44).

The Celgene Defendants move to dismiss these allegations. First, the Celgene Defendants argue that Celgene's decision not to extract a royalty from Natco is not a cognizable reverse payment under *Actavis*. (Mov. Br. at 31–33). Second, the Celgene Defendants argue that a license to enter before patent expiry is not a reverse payment but just an agreed-upon early entry. (*Id.* at 33–34). They point out that Natco's license to sell generic lenalidomide before Celgene's patents expire benefits consumers and Natco alike, and so does not trigger *Actavis*'s concern with "payment in return *for staying out of the market*." (Reply at 16 (citing *Actavis*, 570 U.S. at 154) (emphasis in original)). In addition, the Celgene Defendants contend that the mere fact that a volume-limit may have disincentivized Celgene from launching an authorized generic is not sufficient to allege a reverse payment. (*Id.* at 19–20). Rather, they contend that the law requires plausible allegations that the brand promised the generic that the brand would not launch an AG and otherwise would have launched the AG—allegations which are absent here. (*Id.*). For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that the volume-limited, royalty free license does not plausibly amount to a reverse payment under *Actavis*.

First, the Court finds that to the extent the Insurer Plaintiffs allege that the royalty-free nature of the Celgene-Natco agreement worked in tandem with the volume-limited nature of the agreement to function as a reverse payment, any such allegations are implausible by the Insurer Plaintiffs' own admissions. In moving to dismiss the Insurer Plaintiffs' reverse payment allegations, the Celgene Defendants interpreted the Insurer Plaintiffs' Amended Complaint as alleging that the Celgene-Natco agreement amounted to a reverse payment in part because it did not require Natco to pay royalties to use Celgene's patents. (Mov. Br. at 29). They describe their interpretation of these allegations as follows: "[t]he theory is that by 'waiving' royalties, rather than charging an alleged 'industry standard' 90% [royalty figure], Celgene made 'a substantial reverse payment' to Natco by allowing it to keep its profits." (*Id.*). The Court agrees with this interpretation of the Insurer Plaintiffs' Amended Complaint.

As already recounted above, the Insurer Plaintiffs allege that the settlement agreement between Celgene and Natco constituted an unlawful reverse payment because it provided Natco with a volume limited, *royalty-free* generic license before full generic competition began, equating to hundreds of millions of dollars in payment to Natco. (Humana Am. Compl. ¶ 341 (emphasis added)). As the Celgene Defendants point out, to support this theory, the Insurer Plaintiffs allege that when a brand launches its own AG through a distributor in a competitive agreement "the industry standard is for the brand to retain 90% or more of the licensed generic profits."[55] (*Id.* ¶ 428 n.168). The Amended Complaint then provides that "[a] rational brand manufacturer in Celgene's position would not *waive these royalties* unless it was getting something in return. Celgene *charged no royalties* to Natco during the limited-volume period because the license was indeed connected to the patent litigation settlement and it was getting something in return: Celgene

[55] Notably, here the Celgene-Natco agreement did not include a provision granting Natco a license to market an AG, but instead allowed Natco to license and sell its own generic lenalidomide.

was buying a delay in full-fledged, robust, generic competition." (*Id.* ¶ 428 (emphasis added); *see also id.* ¶ 427 ("By instead offering a favorable royalty payment as part of a patent litigation settlement, or by waiving it entirely, as Celgene did when settling the Revlimid litigation with Natco, a brand manufacturer makes a substantial reverse payment to the generic manufacturer.")). Based on these allegations, it appears that the Insurer Plaintiffs were indeed alleging that the Celgene-Natco agreement amounted to a reverse payment in part because it did not require Natco to pay royalties to use Celgene's patents.

This interpretation is reinforced by the manner in which the Insurer Plaintiffs value the reverse payment. More specifically, the Insurer Plaintiffs provide an estimate of the reverse payment from Celgene to Natco, which they value at approximately $3.6 billion, as shown below.

	Brand Market (in millions)	Percent of market	Generic-to-brand price ratio	Generic sales (in millions)	Foregone royalties on generic sales (in millions)
Year 1	$8,000	5.0%	100%	$400	$360
Year 2	$8,000	15.0%	100%	$1,200	$1,080
Year 3	$8,000	30.0%	100%	$2,400	$2,160
					Total: $3,600

(*Id.* ¶ 429). To arrive at this calculation, the Insurer Plaintiffs make several assumptions. To start, as described above, under the terms of the settlement agreement, Celgene allowed Natco to sell a limited amount of lenalidomide that would be capped at a mid-single digit percentage of the total lenalidomide capsules dispensed in the United States. (*Id.* ¶ 368). That volume limitation would increase gradually every twelve months until March of 2025, but would not exceed one third of the total lenalidomide capsules dispensed in the U.S. (*Id.*). Consistent with these terms, to value the alleged reverse payment from Celgene to Natco, the Insurer Plaintiffs assume that Natco will be allowed to sell 5% of the total lenalidomide capsules dispensed in the United States in the first year, 15% in the second year, and 30% in the third year. (*Id.* ¶ 429). Next, the Insurer Plaintiffs assume that the total value of the Revlimid market amounts to $8 billion in each year. (*Id.* ¶ 429

n.170). Further, the Insurer Plaintiffs assume that under the agreement, Natco would be able to sell generic lenalidomide for the same price as brand Revlimid because Natco would have no incentive to reduce its prices to increase volume under a volume limited license. (*Id.* ¶ 429 n.170). Finally, to arrive at the value of the reverse payment, the Insurer Plaintiffs multiply the value of total generic sales made by Natco at the same price as brand Revlimid by 90%—the alleged royalty rate at which brand manufacturers will typically grant generic manufacturers licenses to market AGs—yielding a total *foregone royalty* amount or reverse payment in the amount of $3.6 billion. (*Id.* ¶ 429; *id.* ¶ 431 ("The total size of the reverse payment from Celgene to Natco associated with these *foregone royalties* is estimated to be $3.6 billion." (emphasis added))). Based on these calculations, it appears that the Insurer Plaintiffs were indeed alleging that the Celgene-Natco agreement amounted to a reverse payment in part because Celgene waived royalties under the agreement, rather than charging an alleged "industry standard" of 90%.

Nevertheless, at oral argument, the Insurer Plaintiffs clarified that they are *not* alleging that the royalty free nature of the license amounts to a reverse payment. (Tr. of Aug. 18, 2023 Oral Arg. at 137:13–18, 157:23–158:3, & 138:4–11). In fact, they clarified that they are not alleging that Celgene was required to charge Natco an industry standard 90% royalty rate or *any particular royalty at all*. (*Id.* at 172:14–15 ("[W]e are not saying they are required to charge any particular royalty."). Rather, they contend that the royalty free aspect of the license operates *together* with the volume-limited nature of the license to function as a reverse payment. (Humana Am. Compl. ¶ 341; Tr. of Aug. 18, 2023 Oral Arg. at 137:13–18). As an initial matter, as the Celgene Defendants pointed out (Tr. of Aug. 18, 2023 Oral Arg. at 174:9–18), if Celgene was not required to charge Natco *any particular royalty at all*, as the Insurer Plaintiffs contend, then it is not clear to the Court why the Insurer Plaintiffs valued the reverse payment from Celgene to Natco based

on foregone royalties in the amount of 90% on generic sales. (Humana Am. Compl. ¶ 429). Rather, that allegation seems to indicate that the Insurer Plaintiffs are in fact claiming that Celgene made a substantial reverse payment, to Natco in part by "waiving" royalties rather than charging an alleged "industry standard" royalty of 90%. (*Id.*).

Yet, based on the Insurer Plaintiffs' own admission, the royalty free nature of the license, even working in tandem with the volume limited nature of the license, could not plausibly have transferred any value to Natco. Looking first at the royalty-free nature of the license, the Insurer Plaintiffs have conceded that this is insufficient on its own to amount to a reverse payment. (Tr. of Aug. 18, 2023 Oral Arg. at 137:13–18, 138:4–11 & 172:3–15). If by the Insurer Plaintiffs own admission Celgene was not required to charge Natco *any royalty at all*, then it is not clear to the Court what value the royalty-free nature of the license transferred to Natco. In other words, if Celgene was not obligated to charge Natco any royalty whatsoever, then it could not have plausibly transferred any value to Natco by granting it a royalty free license.

Next, the Court is not convinced that the royalty free nature of the license, even working in tandem with the volume limited nature of the license, plausibly transferred any value to Natco. In their Opposition Brief, the Insurer Plaintiffs contend that the volume-limited, royalty free license amounts to a reverse payment because the "[t]he small license ensured that Natco's capped level sales could not effectuate bona fide downward generic price pressure" and "[t]he sales cap also ensured that Celgene would have no reason from 2022 to 2026 to enter the market with its own generic." (Opp. Br. at 18). As such, they argue that because "its unit sales would be capped," Natco would enjoy selling its generic lenalidomide "at multiples higher than with bona fide competition, and the absence of any royalties (*otherwise usually customary and high*) meant it would make hundreds of millions of dollars more than it would have even if it had won the patent

disputes and launched into a competitive marketplace." (*Id.* (emphasis added)). In other words, the Insurer Plaintiffs appear to contend that (i) the volume-limited nature of the license transferred value to Natco by allowing Natco to sell its generic lenalidomide at multiples higher than with bona fide competition and by disincentivizing Celgene from launching an AG and (ii) the royalty free nature of the license further reinforced that transfer of value by allowing Natco to pocket more of the profits it obtained from selling its generic lenalidomide at those allegedly high prices than it otherwise could if Celgene had required Natco to pay a royalty. (*Id.*). To be sure, under a royalty-free agreement, Natco would surely be able to reap more profits from its generic sales of lenalidomide than it otherwise could if it had been obligated to pay Celgene a royalty. However, if by the Insurer Plaintiffs own admission, Celgene was not required to charge Natco *any royalty at all*, then it is not clear to the Court what value the royalty-free nature of the license transferred to Natco, either alone *or* in combination with the volume-limited nature of the license. (Tr. of Aug. 18, 2023 Oral Arg. at 172:3–15). In other words, if Celgene was not obligated to charge Natco any royalty whatsoever, then it could not have plausibly transferred any value to Natco by granting it a royalty free license, even if that royalty free license allowed Natco to capture more profits from its allegedly supracompetitive pricing. This is particularly true, since, as will be discussed below, it is not even plausible that the volume limited nature of the license, standing on its own, could have ensured that Natco could sell its generic lenalidomide "at multiples higher" than it could if Natco had not been volume capped. As such, based on the Insurer Plaintiffs' own admission, the Court is not convinced that the royalty free nature of the license, even working in tandem with the volume limited nature of the license, amounts to a "payment" that was made in "reverse" from Celgene to Natco under *Actavis*.

Further, at oral argument the Insurer Plaintiffs appeared to contend that the royalty free nature of the license reinforced Natco's ability to sell its generic lenalidomide at alleged supracompetitive prices. (Tr. of Aug. 18, 2023 Oral Arg. at 186:18–187:5). When pressed to provide an explanation for this theory, the Insurer Plaintiffs provided the following response: "So theoretically, one could have constructed a royalty structure that would have incentivized Natco to reduce its price, if the royalty changed over time. Say there was a royalty that the lower Natco's price was, the less of a royalty was paid to Celgene." (*Id.* at 187:19–23). However, under the Insurer Plaintiffs' own example, Natco would only be incentivized to drop its prices if the royalty percentage they owed to Celgene under the agreement dropped as well. As the Celgene Defendants pointed out, this makes perfect sense. If Celgene had charged Natco a royalty, it would have been more difficult for Natco to compete on price because Natco's profit margins would be smaller. As such, if Celgene had charged Natco a royalty, Natco would have been incentivized to keep its prices higher, not lower. (*Id.* at 196:14–18). The Insurer Plaintiffs could not explain, however, how a royalty *free* license would reinforce Natco's ability to sell its generic lenalidomide at alleged supracompetitive prices and the Court does not construe any such explanation from the allegations in the Insurer Plaintiffs' Amended Complaint. In sum, the Court finds that to the extent the Insurer Plaintiffs allege that the royalty-free nature of the Celgene-Natco agreement worked in tandem with the volume-limited nature of the agreement to function as a reverse payment, any such allegations are implausible by the Insurer Plaintiffs' own admissions.

Second, the Court finds that the volume limited nature of the Celgene-Natco license does not plausibly amount to a reverse payment under *Actavis*. The Insurer Plaintiffs raise two theories as to how the volume limited nature of the Celgene-Natco agreement amounted to a reverse payment. Pursuant to the first theory, the Insurer Plaintiffs contend that the volume limited nature

of the Celgene-Natco license amounted to a reverse payment because the "[t]he small license ensured that Natco's capped level sales could not effectuate bona fide downward generic price pressure." (Opp. Br. at 18). Under the second theory, the Insurer Plaintiffs contend that the volume-limited nature of the agreement amounted to a reverse payment because the "[t]he sales cap ensured that Celgene would have no reason from 2022 to 2026 to enter the market with its own generic" and as such functioned as de facto promise by Celgene not to launch its own authorized generic. According to the Insurer Plaintiffs, this de facto no-AG promise transferred profits Celgene would have made from its authorized generic to Natco and assured Natco that it would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise would were it competing with an AG. (*Id.*).

The first inquiry under *Actavis* is whether the Insurer Plaintiffs have sufficiently pleaded a "payment" made in "reverse," namely from Celgene to Natco. *Actavis*, 570 U.S. at 156–58; *Lipitor*, 868 F.3d at 252–53; *see also Sergeants Benevolent Ass'n Health & Welfare Fund*, 2016 WL 4992690, at *13 (quoting *Actos*, 2015 WL 5610752, at *11). "If they have not done so, their antitrust claims fail, and the Court need not go any further." *In re Opana ER Antritrust Litig.*, 162 F. Supp. 3d 704, 716 (N.D. Ill. 2016). As the Third Circuit has emphasized, "a reverse payment underlying an *Actavis* antitrust claim need not be in cash form." *Lipitor*, 868 F.3d at 252. Rather, "the reverse payment's legality depends mainly on its economic substance, not its form." *AbbVie Inc.*, 976 F.3d at 356. For the reasons set forth below, the Court finds that the Insurer Plaintiffs have failed to plausibly allege that the volume limited nature of the Celgene-Natco agreement amounted to a "payment" that was made in "reverse" from Celgene to Natco under *Actavis*.

As discussed above, under their first theory, the Insurer Plaintiffs allege that the volume limited nature of the Celgene Natco agreement amounted to a reverse payment because it "ensured

that Natco's capped level sales could not effectuate bona fide downward generic price pressure." (Opp. Br. at 18). More specifically, they allege that because Natco could only sell a limited amount of lenalidomide under the terms of the settlement agreement, it would have no incentive to reduce its prices to increase the volume of its sales. (Tr. of Aug. 18, 2023 Oral Arg. at 210:24–211:7). As a result, the Insurer Plaintiffs allege that the volume-limited license would allow Natco to charge prices "at multiples higher" than it would with no volume cap, thereby keeping prices for both Revlimid and generic lenalidomide at supracompetitive levels. (Humana Am. Compl. ¶ 341; Opp. Br. at 18). As such, the Insurer Plaintiffs identify Natco's expected profits from its limited-volume generic lenalidomide sales at allegedly supracompetitive prices under the settlement agreement as the reverse payment that induced Natco to accept a later entry date. (Humana Am. Compl. ¶¶ 341 & 418–31). However, these allegations do not plausibly allege a "payment" that was made in "reverse" from Celgene to Natco under *Actavis*.

Though the Insurer Plaintiffs allege that the volume-limited license transferred value to Natco by allowing it to sell its generic lenalidomide at allegedly supracompetitive prices, it is not plausible that the volume limited nature of the license, standing on its own, could have ensured that Natco could sell its generic lenalidomide "at multiples higher" than it could have if Natco had not been volume capped. Here, the Insurer Plaintiffs do not allege that Celgene granted Natco an exclusive license during the entire relevant license period. Accordingly, at the time Celgene settled with Natco, it was still possible that other generics could enter the market with generic versions of lenalidomide before patent expiry and during the term of Natco's volume limited license. In fact, the Insurer Plaintiffs allege that Celgene later settled with numerous other generic manufacturers under terms that would allow those generics to enter the market before patent expiry and during Natco's relevant license period. (*Id.* ¶ 430). As such, the only way that Natco could have been

assured, under the terms of the settlement agreement, that it could sell its generic lenalidomide "at multiples higher than with bona fide competition" (Opp Br. at 18), is if Natco knew that it was not going to face any real competition from other generic manufacturers for any sales of generic lenalidomide throughout the entire relevant license period. Otherwise, Natco faced the risk that its prices could be undercut by a later entering generic during the term of its license. And, regardless of whether it was volume capped or not, if Natco wanted to compete effectively it would be forced to match its competitors' prices to ensure that its sales were not wholly diverted to those competitors. This principle is supported by the Insurer Plaintiffs' own allegations. In describing a world with competitive conditions, the Insurer Plaintiffs allege that typically the first filing generic—the generic that is entitled to a 180-day period of exclusivity—makes about 80% of all of the profits that it will ever make on the product in the first 180-days when there is no competition from other generics. (Humana Am. Compl. ¶ 77). However, they allege that "[o]nce [other] generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs." (*Id.* ¶ 78; *see also id.* ¶ 434 (describing how under allegedly competitive conditions Natco can only capture a large portion of the market during its 180-days of exclusivity in the absence of competition from other third-party generics)). In other words, even under allegedly competitive conditions, the Insurer Plaintiffs' own allegations acknowledge that a generic manufacturer can only keep its prices high and profits large as long as it knows it will not face additional generic competition.

Accordingly, even though Natco was volume-capped under the settlement agreement, the only way that Natco could have been assured that it could sell its generic lenalidomide "at multiples higher" than it could if Natco had not been volume capped is if Natco knew that it was not going

to face any real competition from other generic manufacturers for any sales of generic lenalidomide throughout the entire relevant license period. Yet, the Insurer Plaintiffs do not allege that the Celgene-Natco agreement provided Natco any such assurance. More specifically, the Insurer Plaintiffs do not allege that Celgene promised, under the agreement, that it would not license later-filing generics to enter the market on terms that would allow them to compete with Natco. (*See, e.g.*, *id.* ¶¶ 341, 368 & 418–44). Even if it had, it is not the volume limited nature of the license that would have transferred value to Natco as the Insurer Plaintiffs allege, but rather the promise that Natco would not face any additional generic competition after it entered the market under the agreement and as such would not need to discount its prices to compete with additional potential generic entrants. (*Id.* ¶ 78). As such, even accepting the Insurer Plaintiffs' allegations as true, it is not plausible that the volume limited nature of the license could have ensured that Natco could sell its generic lenalidomide "at multiples higher" than it could if Natco had not been volume capped and thereby transferred value to Natco. *See In re Opana ER Antritrust Litig.*, No. 14-10150, 2016 WL 738596, at *8 (N.D. Ill. Feb. 25, 2016) ("[T]o raise a right to relief above the speculative level, [plaintiffs] must provide some reliable foundation to show an estimated value of the reverse payment and how that estimate was calculated").

To be sure, the Insurer Plaintiffs appear to allege that Natco would not face any real competition from other generic manufacturers for any sales of generic lenalidomide throughout the entire relevant license period because Celgene later entered into settlement agreements with other generic manufacturers under volume limited licenses as well. (Humana Am. Compl. ¶ 430). In particular, the Insurer Plaintiffs allege that Celgene settled at least four later patent infringement suits with Dr. Reddy's, Alvogen, Cipla, and Sun, such that none of those generics could enter the market until sometime after the March 2022 date agreed to in the Celgene-Natco agreement,

ensuring that Natco would receive the most favorable entry date. (*Id.* ¶¶ 376–417 & 430). In exchange for ending those patent litigations, Celgene allegedly carved out a portion of its monopoly to share with Dr. Reddy's, Alvogen, Cipla, and Sun. More specifically, the Insurer Plaintiffs allege that Celgene also granted Dr. Reddy's, Alvogen, Cipla, and Sun licenses to sell certain volume-limited amounts of generic lenalidomide sometime after the March 2022 entry date provided to Natco in the Celgene-Natco agreement. (*Id.* ¶¶ 376–417). While the Insurer Plaintiffs do not challenge these later agreements as anticompetitive reverse payment settlements (*id.* ¶ 571 n.214), they allege that those later agreements served to shore up the anticompetitive terms (and the attendant windfall of profits) of the Celgene-Natco agreement. (*Id.* ¶ 376). They contend that because a "seller with a volume limit has no incentive to compete on price[,] [a]dding generic sellers with volume limits will put no downward pressure on price." (*Id.* ¶ 423). Accordingly, the Insurer Plaintiffs appear to allege that Natco would not face any real competition from other generic manufacturers throughout the license period because Celgene only allowed other generic manufacturers to enter the market under volume limited licenses as well, ensuring that no generic manufacturer would have the incentive to compete on price.

As an initial matter, the Court is not convinced by the Insurer Plaintiffs' conclusory allegation that because a "seller with a volume limit has no incentive to compete on price[,] [a]dding generic sellers with volume limits will put no downward pressure on price." (*Id.* ¶ 423). In fact, this bare assertion seems to be contradicted by the remainder of the Insurer Plaintiffs' own allegations. More specifically, the Insurer Plaintiffs allege that under "competitive conditions, there are typically three products available during the 180-day generic exclusivity period: the first-to-file generic's product, the brand's authorized generic product, and the brand product." (*Id.* ¶ 441). They explain that the two generic products quickly "capture most of the market" and

"compete on price, bringing it down to approximately 46.5% of the brand price, so purchasers benefit." (*Id.*). They further allege that "once [additional] generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs." (*Id.* ¶ 78). In other words, under the Insurer Plaintiffs' own pleadings, when there is more generic product available than there is demand for the generic, "the competitive process accelerates . . . driving prices down." (*Id.*). However, though the Insurer Plaintiffs plead that the entry of additional generic competitors exerts a deflationary force on pricing under "competitive conditions," they provide absolutely no support for their assertion that adding generic sellers with volume limits would put no downward pressure on price whatsoever. If the total supply of generic lenalidomide in the market exceeds total demand for that product, a generic that is at risk of being unable to sell its entire supply of lenalidomide will be incentivized to lower its prices to minimize excess inventory and ensure that its sales are not wholly diverted to another competitor, regardless of whether it is volume limited or not. Here, the Insurer Plaintiffs do not allege that the total supply of generic lenalidomide that Natco and other volume-limited generic manufacturers could collectively sell in the market under their relevant licenses would not exceed the demand for generic lenalidomide in the market. As such, the Court is not convinced by the Insurer Plaintiffs' conclusory allegation that adding generic sellers with volume limits would put *no* downward pressure on price. (*Id.* ¶ 423).

Nevertheless, to the extent the Insurer Plaintiffs allege that Natco would not face any real competition from other generic manufacturers throughout the entire relevant license period because Celgene only allowed other generic manufacturers to enter the market under volume-limited licenses as well, the Insurer Plaintiffs do not allege that the Celgene-Natco settlement itself

guaranteed Natco any such lack of competition. The agreement was between Celgene and Natco and did not, according to the Insurer Plaintiffs' own allegations, bind any other generic manufacturer. As such, even if Celgene's volume limited settlement agreements with later generic manufacturers had the effect of ensuring that no other generics—who likewise would be volume-capped—would be incentivized to compete with Natco on price, no such assurance was transferred to Natco by way of its own volume-limited agreement with Celgene.

Further, it is not plausible that the volume limited nature of the Celgene-Natco license, standing on its own, transferred any value to Natco that Natco could not have obtained if it had been permitted by Celgene to enter the market unrestrained. As recounted above, the Insurer Plaintiffs allege that because Natco could only sell so much lenalidomide under the settlement agreement, it would have no incentive to reduce its prices to increase volume and could thereby charge prices "at multiples higher" than it could with no volume cap. (Tr. of Aug. 18, 2023 Oral Arg. at 210:17–211:7; Humana Am. Compl. ¶ 341; Opp. Br. at 18). As such, they allege that Natco is substantially "better off" under the volume limited license because, even though Natco was only permitted to capture a small percentage of the generic lenalidomide market, it could sell its generic lenalidomide under those volume restraints at supracompetitive prices. (Humana Am. Compl. ¶¶ 429 & 438). However, even if Celgene had permitted Natco to enter the market unrestrained—as the Insurer Plaintiffs allege Celgene should have done (Tr. of Aug. 18, 2023 Oral Arg. at 210:15–211:7) and as Natco would have had the right to do had it prevailed in litigation—Natco would still have had the option under such a scenario to cap the amount of lenalidomide it produces itself. If selling lenalidomide under the volume restraints imposed by the Celgene-Natco agreement were more valuable to Natco than selling that lenalidomide unrestrained—as the Insurer Plaintiffs allege it was—Natco would have no reason to exceed those volume thresholds even if it

was permitted to enter the market with no volume restraints.[56] Rather, it would simply be motivated to produce and price its lenalidomide in a manner that maximized its profits.

If anything, such a volume cap could only have taken value *away* from Natco by preventing it from selling an amount of lenalidomide that would maximize its profits. This is illustrated by the Insurer Plaintiffs' own pleading, which undercuts any allegation that the volume limited nature of the Celgene-Natco agreement functioned as a reverse payment. As shown below, when providing an estimate of the reverse payment from Celgene to Natco, the Insurer Plaintiffs allege that the value of the reverse payment to Natco got larger as its licensed volumes increased.

	Brand Market (in millions)	Percent of market	Generic-to-brand price ratio	Generic sales (in millions)	Foregone royalties on generic sales (in millions)
Year 1	$8,000	5.0%	100%	$400	$360
Year 2	$8,000	15.0%	100%	$1,200	$1,080
Year 3	$8,000	30.0%	100%	$2,400	$2,160
				Total:	**$3,600**

(Humana Am. Compl. ¶ 429). The Insurer Plaintiffs do not provide any allegations to explain how it could simultaneously be true that a volume limited license is what creates a reverse payment but also that increased volume confers an even larger transfer of value. Rather, the Insurer Plaintiffs' own allegations indicate that the volume restraints imposed by the Celgene-Natco agreement *prevented* Natco from obtaining greater sales and as such took value *away* from Natco. (*Id.*). Accordingly, the Insurer Plaintiffs' theory that the volume limited license functioned as a reverse payment is contradicted by their own allegations. *See, e.g.*, *In re Bystolic Antitrust Litig.*, 583 F.

[56] To be sure, the Insurer Plaintiffs also contend that the volume-limited license amounted to a reverse payment because it disincentivized Celgene from launching its own authorized generic. (Humana Am. Compl. ¶ 443; Opp. Br. at 19). As such, the Insurer Plaintiffs might argue that Natco would not have had the incentive to cap itself even if allowed to enter the market unrestrained, because Natco would not have received the same value under unrestrained conditions that it would have received under a volume limited license, namely an agreement that functionally operated as a promise by Celgene not to launch its own authorized generic. Nevertheless, as explained below, it is not plausible that the volume limited nature of the Celgene-Natco agreement could have disincentivized Celgene from launching its own authorized generic throughout the entirety of Natco's relevant license period. As such, this argument has no merit.

Supp. 3d 455, 479–80 (S.D.N.Y. 2022) ("[T]o state a claim under *Actavis*, a plaintiff must allege more than a general statement simply asserting that a reverse payment is large and unjustified . . . [r]ather, the plaintiff must plead *facts* that would support the claim that the reverse payment was 'large' and 'unjustified,' i.e., that it was not simply possible that the defendants engaged in the anticompetitive conduct of paying the generic manufacturer to forego entering the market but that it was plausible.") (emphasis in original)).

To support their allegations that the volume-limited nature of the Celgene-Natco agreement amounts to a reverse payment under *Actavis*, the Insurer Plaintiffs cite to the Northern District of California court's decision in *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829 (N.D. Cal. 2021), which they claim held that allegations that a "brand company made a large and unjustified payment to a competitor by providing a limited license to sell a constrained amount of a generic were sufficient to withstand a motion to dismiss." (Opp. Br. at 20). The Court, however, finds *Xyrem* distinguishable. In *Xyrem*, the plaintiffs challenged as unlawful settlement agreements entered into between brand manufacturer, Jazz, and later entering generic companies which contained three alleged reverse payments: (i) a multi-million dollar cash payment from Jazz to each generic defendant; (ii) a limited license to later generics to sell a constrained supply of authorized generic which was capped at a low-single digit market share and required a royalty payment, as a percentage of sales, that increased over time; and (iii) an acceleration clause. *Xyrem*, 555 F. Supp. 3d at 845–46. The court ultimately found that the plaintiffs had plausibly alleged that the defendant made reverse payments. In making that finding, the court specifically rejected the defendants' argument that the non-cash payments, such as the volume-limited sales provision, simply permitted those companies to enter the market before patent expiry, "first with volume-limited AG sales and then with full entry 2.5 years later" because the value of each of Jazz's

agreements with the later generic defendants was allegedly "at least" in the "tens of millions of dollars." *Id.* at 864. (internal quotation marks omitted). It rejected the defendants' argument that such non-cash payments were not large and unexplained. The court pointed out that the plaintiffs sufficiently alleged that such non-cash payments were extremely valuable and exceeded litigation costs because each percent of market share that Jazz allocated to the generic defendants allegedly represented about $13.5 million per year. *Id.* at 864–65. However, as the Celgene Defendants point out, while in *Xyrem* Jazz gave the later generics a limited license to sell a constrained supply of AG, it did so under a provision that *also* required a royalty payment, as a percentage of sales, that increased over time, thereby incentivizing the generic to charge higher prices. (Reply at 17 (citing *Xyrem*, 555 F. Supp. 3d at 863)). As the Celgene Defendants note, no such royalty structure exists here—in fact, as recounted above the Celgene-Natco agreement was royalty *free*.[57] Further, other than pointing to allegations which stated that Jazz's agreements with the later generic defendants were "at least" in the "tens of millions of dollars," the court in *Xyrem* did not otherwise explain why the volume limited AG sales provision amounted to a reverse payment, standing on its own. However, "to state a claim under *Actavis*, a plaintiff must allege more than a general statement simply asserting that a reverse payment is large and unjustified." *Bystolic*, 583 F. Supp. 3d at 479–80. Here, for the reasons stated above, the Insurer Plaintiffs have failed to do so. As such, their reliance on *Xyrem* is unavailing.

The Insurer Plaintiffs have not directed this Court to any other case law which has found that a volume-limited license amounts to a reverse payment. Without any legal authority or factual

[57] At oral argument the Insurer Plaintiffs argued that even though the volume limited agreement in *Xyrem* contained a royalty structure, which is absent here, the royalty structure at issue in *Xyrem* had the same effect as the volume-limited agreement at issue in this case in removing any incentive to compete on price. (Tr. of Aug. 18, 2023 Oral Arg. at 202:11–15). However, as already described above, it is not plausible that the volume limited nature of the Celgene-Natco agreement, standing on its own, disincentivized Natco from competing on price. As such, the Court is not persuaded by the Insurer Plaintiffs' argument.

basis for doing so in this case, the Court declines to expand *Actavis*'s holding to accommodate the Insurer Plaintiffs' implausible allegations. As such, the Court finds the Insurer Plaintiffs' first theory, namely that that the volume limited nature of the Celgene-Natco license amounted to a reverse payment because the "[t]he small license ensured that Natco's capped level sales could not effectuate bona fide downward generic price pressure," implausible. (Opp. Br. at 18).

As discussed above, under their second theory, the Insurer Plaintiffs allege that the volume limited nature of the Celgene Natco agreement amounted to a reverse payment because the sales cap "ensured that Celgene would have no reason from 2022 to 2026 to enter the market with its own generic." (*Id.*). As the Insurer Plaintiffs explain, typically in a competitive environment a brand manufacturer is motivated to launch an AG to limit the number of unit sales that it loses to the first generic entrant. (*Id.* at 19; Humana Am. Compl. ¶ 441). They allege that a volume-limited license, however, destroys the incentive for a brand to launch its own generic because the brand has already capped the number of pills the generic can sell. (Humana Am. Compl. ¶ 443). As such, the Insurer Plaintiffs contend that the volume-limited license operated as a promise by Celgene not to launch its own AG. (Opp. Br. at 19). Further, they allege that through this de facto no-AG agreement, Celgene transferred the profits it would have made from its AG to Natco and assured Natco that it would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise could were it competing with an AG, proving very valuable to Natco. (*Id.* ¶ 443; Opp. Br. at 19). For the following reasons, the Court finds that these allegations, again, do not plausibly allege a "payment" that was made in "reverse," from Celgene to Natco under *Actavis*.

To be sure, in *King Drug*, the Third Circuit found that a no-AG agreement could plausibly amount to a reverse payment. *King Drug*, 791 F.3d at 403. In so holding, the Third Circuit explained that even though the brand manufacturer did not pay the generic cash under the

agreement, the no-AG agreement was "likely to present the same types of problems as reverse payments of cash" because it could have been worth millions of dollars, if not hundreds of millions of dollars, to the generic. *Id.* at 404. The court noted that "[a]bsent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand." *Id.* at 405. As such, the brand's commitment not to produce an AG transferred to the generic "the profits [the brand] would have made from its authorized generic." *Id*. The Third Circuit reasoned that the agreement may have been "something more than just an agreed-upon early entry"—it may have been "pay-for-delay." *Id.*

Here, however, the Insurer Plaintiffs have not alleged that Celgene promised not to produce an AG under the Celgene-Natco settlement agreement. Instead, they merely allege that the volume-limited nature of the license disincentivized Celgene from launching its own AG throughout the entirety of Natco's relevant license period, thereby conveying value to Natco. The Court is not convinced. As an initial matter, the Insurer Plaintiffs' allegations do not plausibly indicate that the volume limited license, standing on its own, conveyed value to Natco by disincentivizing Celgene from launching its own AG throughout the entire relevant license period. This is because, as mentioned before, the Insurer Plaintiffs do not allege that Celgene granted Natco an exclusive license during the entire relevant license period. Accordingly, at the time Celgene settled with Natco the parties understood that it was still possible that other generics could enter the market during the term of Natco's volume limited license. In fact, the Insurer Plaintiffs allege that Celgene later settled with numerous other generic manufacturers under terms that would allow those generics to enter the market before patent expiry and at some point during Natco's relevant license period. (Humana Am. Compl. ¶¶ 376–417, 430 & 434). If other generic manufacturers could enter the market during the term of Natco's volume limited license and

compete with Celgene, then Celgene would have been motivated to launch its own authorized generic to compete with those generic manufacturers. The Insurer Plaintiffs' own allegations emphasize that "brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales (from the branded product to a generic/AG product) they would otherwise lose entirely to the generic entrant." (*Id.* ¶ 51). While the volume limited license under the Celgene-Natco agreement capped the amount of generic lenalidomide Natco could sell, the Insurer Plaintiffs do not allege that it also controlled the manner and terms under which *other* generic manufacturers could compete with Celgene through the entirety of Natco's relevant license period.[58] The agreement was between Celgene and Natco and did not, according to the Insurer Plaintiffs' own allegations, bind any other generic manufacturer. In other words, the agreement left open the possibility that other generic manufacturers could enter the market during the term of Natco's volume limited license and compete with Celgene, thereby giving Celgene an incentive to launch its own AG. Thus, it is not plausible that the volume limited nature of the Celgene-Natco agreement, by itself, could have assured Natco that Celgene would be disincentivized from launching its own AG throughout the entirety of Natco's relevant license period, thereby conveying value to Natco. Further, even if the Insurer Plaintiffs' allegations were plausible, and the volume limited license, standing on its own, did somehow disincentivize Celgene from launching its own AG, "*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible." *King Drug*, 791 F.3d at 408–09. "*Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Actos*, 2015 WL 5610752, at *16.

[58] While the Insurer Plaintiffs allege that Celgene later entered into settlement agreements with other generic manufacturers under volume limited licenses as well (Humana Am. Compl. ¶¶ 376–417 & 430), they do not allege that the Celgene-Natco agreement itself controlled the manner and terms under which *other* generic manufacturers could compete with Celgene through the entirety of Natco's relevant license period.

The Insurer Plaintiffs cite to three cases to support their argument that a provision that only disincentivizes a brand company from launching its own authorized generic can plausibly amount to a reverse payment: (i) *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829 (N.D. Cal. 2021); (ii) *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639 (D. Mass. 2020); and (iii) *In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F. Supp. 3d 418 (E.D. Va. 2019). (Opp. Br. at 19–20 n.66).[59] All of these cases are distinguishable. To start, in *Xyrem*, the court found that the plaintiffs had plausibly alleged an unlawful reverse payment between brand manufacturer (Jazz) and generic manufacturer (Hikma) based on the existence of an implicit no-AG agreement. *Xyrem*, 555 F. Supp. 3d at 852–55. There, plaintiffs pointed to a number of provisions in the agreement that disincentivized Jazz from marketing its own AG. *Id.* at 856. To start, they alleged that Jazz promised not to license its AG through any third-party during Hikma's first 180 days of selling the Hikma AG. *Id.* Though Jazz technically reserved the theoretical option of marketing its own AG, the plaintiffs alleged that this provision nevertheless disincentivized Jazz from launching its own AG because Jazz's statements indicated that it had a limited in-house manufacturing capacity and industry custom indicated that brand manufacturers do not typically launch AG's themselves. *Id.* at 856–58. Further, they alleged that under the agreement Hikma was obligated to pay increasingly higher percentages of royalties to Jazz as Hikma's market share increased. *Id.* at 858. According to the plaintiffs in that case, this undermined Jazz's own economic interest in selling its own AG because the launch of a Jazz AG would take market share from Hikma and thereby reduce Hikma's royalty obligations to Jazz under the agreement. *Id.* The court found plausible the plaintiffs' allegations that these provisions amounted to an implicit no-AG agreement that conveyed value to

[59] While the Insurer Plaintiffs also cite to *Wellbutrin XL*, 868 F.3d at 161; *Lipitor*, 868 F.3d at 252; *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); and *King Drug*, 791 F.3d at 394 (Opp. Br. at 19–20 n.66), those cases all involved explicit no-AG agreements. As such, those cases are distinguishable.

Hikma and plausibly operated as a reverse payment. *Id.* at 858–59. No such similar allegations exist in this case. More specifically, the Insurer Plaintiffs do not plead that Celgene promised not to license its own AG through a third party. Nor do the Insurer Plaintiffs allege that Natco was obligated, under the agreement, to pay increasingly higher percentages of royalties to Celgene as Natco's market share increased, thereby reducing Celgene's incentive to launch its own AG. In fact, as recounted above, the Celgene-Natco agreement was royalty free. As such, the Court finds *Xyrem* distinguishable.

Likewise distinguishable is the court's decision in *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639 (D. Mass. 2020). In *Intuniv*, the court sitting in the District of Massachusetts found that the plaintiffs had raised genuine issues of material fact as to whether brand manufacturer (Shire) made large, unjustified payments to generic manufacturer (Actavis). *Intuniv*, 496 F. Supp. 3d at 661–62. There, the plaintiffs challenged a settlement agreement under which Shire would receive a 25% royalty during Actavis' first 180 days on the market, as long as Actavis was the only generic producing Intuniv on the market. *Id.* at 653, 669. Because under the terms of the agreement, Actavis' royalty obligations would terminate if Shire launched an AG, the plaintiffs argued that the royalty provision acted as an enforcement mechanism for an implicit no-AG agreement. *Id.* at 670–72. Further, under the agreement Shire could not authorize or license a third party to market or sell AG product at any time before the end of Actavis' 180 days of exclusivity or another generic entering the market. *Id.* at 668–69. The plaintiffs contended that this too contributed to an implicit no-AG agreement because brand companies do not market their own AG products themselves. *Id.* Though under the terms of the agreement Shire retained the right itself, or through an affiliate, to market at any time an AG product, the court found that the provisions of the agreement, coupled with other indirect evidence, created material disputes of fact

as to whether Shire and Actavis entered into an implicit no-AG agreement. *Id.* at 671–72. Again, no such similar settlement terms are alleged to have existed in this case. More specifically, the Insurer Plaintiffs do not plead that Celgene promised not to license its own AG through a third party. Nor do the Insurer Plaintiffs allege that Natco's royalty obligations to Celgene would terminate if Celgene launched its own AG. In fact, as recounted above, the Celgene-Natco agreement was royalty free. As such, the Court finds *Intuniv* distinguishable.

Finally, the court's decision in *In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F. Supp. 3d 418 (E.D. Va. 2019) is also factually distinct from the present action. In *Zetia*, the court found that the plaintiffs plausibly pled the existence of a reverse payment based on a no-AG agreement. In reaching this conclusion, the court found that the settlement agreement at issue could plausibly be read as a no-AG agreement because the agreement only reserved the brand manufacturer's ability to sell a branded and not a generic product. *Zetia*, 400 F. Supp. 3d at 428. The court also found plausible plaintiffs' allegations that other circumstantial evidence corroborated the existence of the no-AG agreement, including the fact that the generic claimed exclusivity on release of its generic product and that the brand manufacturer failed to release an authorized generic throughout the generic's period of exclusivity. *Id.* at 430–31. Again, no such similar allegations are present here.

Without any legal authority or factual basis for doing so in this case, the Court declines to expand *Actavis*'s holding to find that the volume limited license amounted to a reverse payment simply because it may have disincentivized Celgene from launching an authorized generic. As the Celgene Defendants point out, if an allegation that an agreement merely disincentivized a brand manufacturer from launching its own authorized generic sufficed to plead a reverse payment, countless settlement terms could be characterized as disincentivizing an authorized generic. (Reply at 20). In fact, a similar inference could be drawn from a settlement in which a generic

manufacturer is permitted to enter the market before patent expiry but also agrees to respect the patents for a period of time and does not receive any corresponding payment—while the generic stays off the market, the patent owner would have no incentive to launch its own authorized generic. (*Id.* at 19–20). Yet, the Supreme Court's analysis in *Actavis* emphasized that such patent "settlements taking [ ] commonplace forms have not been thought [to be] subject to antitrust liability" and that the *Actavis* decision "do[es] not intend to alter that understanding." *Actavis*, 570 U.S. at 152; *see also Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is . . . classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements.").

In sum, the Insurer Plaintiffs have failed to plausibly allege that the volume limited, royalty free license in this case was a reverse payment within the meaning of *Actavis*. As described above, it is not plausible that the volume limited license allowed Natco to charge prices "at multiples higher" than it could have had it not been subject to a volume-cap. Nor is it plausible that the volume limited license disincentivized Celgene from launching its own AG, thereby transferring value to Natco. Further, the Insurer Plaintiffs provide no allegations that plausibly indicate that the royalty-free license reinforced Natco's ability to charge prices "at multiples higher" than it would have had it not been subject to a volume cap. In fact, by the Insurer Plaintiffs own admission, Celgene was not required to charge Natco *any royalty at all*, indicating that the royalty-free nature of the license could not have plausibly transferred any value to Natco. Though the Insurer Plaintiffs plead that Natco is substantially better off under the volume limited license (Humana Am. Compl. ¶¶ 429 & 438), their allegations simply do not support this bald assertion.

See, e.g., *Bystolic*, 583 F. Supp. 3d at 479–80. Pursuant to the terms of the settlement agreement, Celgene licensed Natco to enter the market before Celgene's patents expired, first at limited volumes, and then without restriction. (Humana Am. Compl. ¶ 368). At its core, this volume limited license simply granted Natco a compromise date of generic entry. And *Actavis* "expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb." *King Drug*, 791 F.3d at 407 (internal quotation marks omitted). As described above, the volume-limited, royalty free license did not provide any payment from Celgene to Natco. In other words, Natco received no compensation from Celgene, "but rather, w[as] compensated only through the market when [it] began selling [its] generic product" under the terms of the volume limited, royalty free agreement. *Actos*, 2015 WL 5610752, at *15.[60] As such, the effect of Celgene's volume-limited license to Natco "was to increase, not restrain competition by bringing competitors into the market when patents otherwise prohibited the competition." *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 841 (N.D. Ill. 2020), *aff'd sub nom. Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022).[61] As such, the

[60] In their Opposition Brief the Insurer Plaintiffs contend that recent events show continued supracompetitive pricing when capped volume entry occurs and cite to figures that were not alleged in their Amended Complaint. (Opp. Br. at 21). Previously unpleaded allegations presented for the first time in an opposition brief are not properly considered by the Court when ruling on a 12(b)(6) motion. As such, the Court does not consider these arguments. *Frederico v. Home Depot*, 507 F.3d 188, 201–02 (3d Cir. 2007) ("[W]e do not consider after-the-fact allegations in determining the sufficiency of [a] complaint under Rule[ ] . . . 12(b)(6).").

[61] Finally, to the extent that the Insurer Plaintiffs attempt to analogize this case to the facts alleged in (i) *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); (ii) *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017); and (iii) *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327 (3d Cir. 2020), that argument also fails. The settlement agreements in each of these cases contained a payment in reverse that is distinct from the volume-limited, royalty-free license at issue in this case. As already recounted above, in *King Drug*, the brand manufacturer expressly promised not to launch its own authorized generic, even though it had the incentive to do so, thus transferring to the generic "the profits [the brand] would have made from its authorized generic" and making "the settlement something more than just an agreed-upon early entry." *King Drug*, 791 F.3d at 405. In *Lipitor*, the brand resolved a damages claim against the generic regarding a separate drug, even though the brand had reason to believe that damages claim was worth hundreds of millions of dollars. *Lipitor*, 868 F.3d at 253. And in *AbbVie*, the brand provided the generic with a lucrative supply agreement on an unrelated drug. *AbbVie*, 976 F.3d at 356–57. As the Celgene Defendants point out, all of these cases "share what this one lacks: 'highly unusual' consideration." (Reply at 17). As such, these cases do not alter the Court's conclusion.

Insurer Plaintiffs have failed to plead that the volume limited, royalty free license granted by Celgene to Natco amounted to a reverse payment within the meaning of *Actavis*.

The MFE Clause. The Insurer Plaintiffs next allege that the settlement agreement between Celgene and Natco amounted to a reverse payment because it contained an acceleration or MFE clause. (Humana Am. Compl. ¶ 341). As recounted above, the MFE clause permits Natco to enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement, if a later (non-settling) generic is successful in invalidating Celgene's unexpired patents. (*Id.* ¶¶ 432–33). The Insurer Plaintiffs raise two theories as to how the MFE clause under the Celgene-Natco agreement amounted to a reverse payment. Pursuant to the first theory, the Insurer Plaintiffs allege that the MFE clause operated as a reverse payment because it eliminated the risk that Natco loses its lucrative exclusivity period. (*Id.* ¶ 433). Under the second theory, the Insurer Plaintiffs allege that the MFE clause operated as a reverse payment because it disincentivized later generics from challenging Celgene's patents. (*Id.* ¶ 432).

The Celgene Defendants move to dismiss these allegations, contending that the MFE clause provided for in the settlement is not a reverse payment. (Mov. Br. at 34–38). To start, the Celgene Defendants argue that the possibility of Natco obtaining earlier entry plainly does not render an acceleration provision a "reverse payment" under *Actavis* because that case "took issue only with 'payment[s] in return for staying *out of* the market,' 570 U.S. at 154," and "was not concerned with settlements allowing a patent challenger to enter the market *sooner*, which redounds 'to the consumer's benefit.'" (Mov. Br. at 35). Additionally, though the Insurer Plaintiffs allege that the acceleration clause disincentivized later filers from challenging Celgene's patents, the Celgene Defendants note that the Insurer Plaintiffs' own allegations squarely undermine this argument because after the public announcement of the challenged agreement *14* other companies filed

ANDAs on Revlimid, indicating that no generic was "disincentivized" from challenging Celgene's patents. (*Id.* at 37 (citing Humana Am. Compl. ¶¶ 370 & 378)). For the reasons set forth below, the Court finds that the MFE clause did not amount to a reverse payment under *Actavis*.

As discussed above, under their first theory, the Insurer Plaintiffs allege that the MFE clause operated as a reverse payment because it eliminated the risk that Natco would lose its 180-day period of exclusivity, which proved very valuable to Natco. (Humana Am. Compl. ¶ 433). As recounted above (*supra* at 14–20), as the first-filer of the lenalidomide ANDA, Natco was entitled to a 180-day period of exclusivity from the first commercial marketing of its drug, during which no other generic manufacturer could enter the market. (Humana Am. Compl. ¶¶ 347 & 433); *see* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). A first-filer, however, can forfeit this exclusivity period if it fails to launch its generic product within 75 days of a court entering a final decision invalidating the brand's patents on the drug. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). In other words, if another generic manufacturer later defeated Celgene's Revlimid patents, Natco would have 75 days to launch its generic lenalidomide or else forfeit its 180-day exclusivity period. (Humana Am. Compl. ¶ 433). The MFE clause ensured Natco that it could enter the market early if a later (non-settling) generic were successful in invalidating Celgene's patents. (*Id.* ¶¶ 432–33). As such, the Insurer Plaintiffs allege that the MFE clause would permit Natco to enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement in the event the patents were invalidated and retain its 180-day period of exclusivity, which was extremely valuable to Natco. (*Id.*).

These allegations do not plausibly allege a reverse payment under *Actavis*. Even though the MFE clause ensured that Natco would not be at risk of forfeiting its 180-day period of exclusivity—which was extremely valuable to Natco—it did not provide anything of value to

Natco that Natco was not already entitled to pursuant to the statutory scheme of the Hatch-Waxman Act. More specifically, as already discussed, as the first-filer of the lenalidomide ANDA, Natco was entitled to a 180-day period of exclusivity from the first commercial marketing of its drug, during which no other generic manufacturer could enter the market. (Humana Am. Compl. ¶¶ 347 & 433); *see* 21 U.S.C. § 355(j)(5)(B)(iv). Under the statute, Natco was entitled to its 180-day period of exclusivity even if a later generic filer invalidated Celgene's patents. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Though, as discussed already, a first filer may forfeit its exclusivity in several ways, here the Insurer Plaintiffs do not plead that Natco forfeited any such exclusivity. In fact, they allege that Natco retained this period of exclusivity. (Humana Am. Compl. ¶ 97 n.50 & 98; Tr. of Aug. 18, 2023 Oral Arg. at 232:12–25, 239:5). As such, this case is unlike other cases where a plaintiff alleged that a settlement conferring acceleration rights was anticompetitive because the first-filer had forfeited rights to exclusivity under the applicable regulatory scheme. *In re HIV Antitrust Litig.*, 656 F. Supp. 3d 963, 1002–03 (N.D. Cal. 2023). By ensuring that Natco would not be at risk of forfeiting its lucrative exclusivity period in the event that a later (non-settling) generic was successful in invalidating Celgene's unexpired patents, the MFE clause merely preserved the status quo, and did not transfer to Natco anything of value that it could not have obtained but-for the settlement agreement.[62] As a result, the MFE clause could not have plausibly provided Natco with any "payment," by ensuring that Natco would not be at risk of forfeiting its 180-day period of exclusivity.

[62] At oral argument, when asked if the MFE clause was merely preserving the status quo, the Insurer Plaintiffs stated that it was not because Natco was only entitled to its 180-day period of exclusivity upon launch, and here Natco did not launch. (Tr. of Aug. 18, 2023 Oral Arg. at 227:20–228:11). The Court finds this argument unavailing. To be sure, a first filer's 180-day period of exclusivity commences from the first commercial marketing of its drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv). However, the mere fact that Natco could not cash in on its 180-day period of exclusivity until the first commercial marketing of its drug does not mean that it was not still entitled to that period of exclusivity, in the absence of the settlement agreement. And here, the Insurer Plaintiffs do not plead that Natco forfeited its exclusivity.

Pursuant to their the second theory, the Insurer Plaintiffs allege that the MFE clause operated as a reverse payment because it disincentivized later generics from continuing to challenge Celgene's Revlimid patents. (Humana Am. Compl. ¶ 432). According to the Insurer Plaintiffs, "[i]f a later (non-settling) generic were to continue the litigation and invalidate [Celgene's] patents, triggering the [MFE] clause, it would allow at least Natco to enter the market early, cutting into the non-settling generic's market share." (*Id.*). "In other words, the challenger would bear 100% of the cost and risk associated with continuing the patent challenge but would enjoy only a fraction of the rewards if it were to succeed." (*Id.*). As such, the Insurer Plaintiffs allege that the MFE clause deterred patent challenges and provided a reverse payment to Natco in the form of an assurance that it would receive the most-favorable entry date. (*Id.*). However, the plausibility of any such theory is squarely undermined by the Insurer Plaintiffs' own allegations. (Mov. Br. at 37–38). More specifically, as the Celgene Defendants point out, the Insurer Plaintiffs allege that after the public announcement of the Celgene-Natco settlement agreement and the challenged MFE Clause, 14 other generic manufacturers filed ANDAs seeking to market generic versions of Revlimid. (Mov. Br. at 37; Humana Am. Compl. ¶¶ 370, 378, 389, 400, 411, 447, 471, 485, 501, 507, 515, 523, 529, 533 & 536). Accordingly, the Insurer Plaintiffs' own allegations indicate that generic manufacturers were not disincentivized from filing ANDAs on Revlimid and challenging Celgene's Revlimid Patents, notwithstanding the public announcement of the MFE clause in the Celgene-Natco agreement. (Mov. Br. at 37–38). The lack of deterrence observed in the generic lenalidomide market is consistent with the fact that, as another court observed, "ANDA filers understand that other manufacturers of generic drugs may also file ANDAs seeking to market their own generic versions of branded drugs, which (after FDA approval) compete not only with the branded drug but also with any ANDA filer's generic product." *In re Sensipar (Cinacalcet*

Hydrochloride Tablets) Antitrust Litig., No. 19-1460, 2020 WL 7022364, at *8 (D. Del. Nov. 30, 2020); *see also Belcher Pharm., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331 n.4 (D. Del. 2019) ("[I]t is not uncommon for multiple ANDAs to be filed on the same patent at the same time . . . ."). Based on the fact that ANDA filers understand the nature of competition in the pharmaceutical market and that the Insurer Plaintiffs' own allegations indicate that generic manufacturers were not disincentivized from filing ANDAs seeking to market generic versions of Revlimid and challenging Celgene's Revlimid Patents, the Court finds that the Insurer Plaintiffs have failed to plausibly allege that the MFE clause operated as a reverse payment because it disincentivized later generics from continuing to challenge Celgene's patents. *See Actos*, 2015 WL 5610752, at *15 (finding that the plaintiffs' theory that acceleration clause had anticompetitive effect of deterring other generics from disputing brand manufacturer's patents implausible where other generics continued to pursue litigation even after the brand entered into settlement agreement with generic that contained acceleration clause).[63]

The Insurer Plaintiffs' remaining arguments to the contrary are unavailing. To start, the Insurer Plaintiffs contend that even if the MFE clause did not deter later generic manufacturers from filing ANDAs, it still deterred them from actually invalidating Celgene's patents and

[63] The Court notes that in *Xyrem*, the court found that an acceleration clause in a settlement agreement plausibly disincentivized other generic manufactures from litigating their patent claims. More specifically, in *Xyrem* the plaintiffs alleged that an acceleration clause transferred value from a brand manufacturer (Jazz) to a generic manufacturer (Hikma) in part because the clause disincentivized other generic manufacturers from litigating their patent claims. *Xyrem*, 555 F. Supp. 3d at 860–62. In moving to dismiss those allegations, the defendants contended that the acceleration clause failed to actually deter generic entry because after Jazz and Hikma settled between 9 to 18 months passed before later generic defendants settled with Jazz. *Id.* at 862. The court rejected this argument, noting that several generics abandoned their challenges to the Xyrem patents after the Hikma settlement and as such the acceleration clause at least plausibly deterred some generics. *Id.* The Court, however, finds *Xyrem* inapposite. To be sure, the Insurer Plaintiffs do allege that Celgene settled with all but one of the generic manufacturers that later filed ANDAs for Revlimid. (Humana Am. Compl. ¶¶ 339, 385, 396, 407, 416, 458, 477, 482, 500, 506, 511, 521, 526, 528, 532 & 535). However, even the earliest of these settlements was executed nearly three years after Celgene announced its settlement agreement with Natco that included the challenged acceleration clause. (*Id.* ¶¶ 370 & 396). As such, the Court does not find it plausible that some of these generic manufacturers abandoned their patent challenges because the acceleration clause diminished the expected payoff from entering the market. *Xyrem*, 555 F. Supp. 3d at 862.

launching their generic products. They contend that the 14 generic manufacturers that filed ANDAs after the Celgene-Natco agreement was announced did not file ANDAs to launch their generic products but only to negotiate an early entry date by way of a settlement agreement with Celgene so that they could share in Celgene's monopoly profits. (Tr. of Aug. 18, 2023 at 229:10–231:7). Even if this theory had any merit, the Insurer Plaintiffs do not allege that when each of the 14 later generic manufacturers filed ANDAs on Revlimid, they had no intention of ever launching their generic product and instead were only motivated to file ANDAs to negotiate an early entry date by way of a settlement agreement with Celgene. In fact, the Amended Complaint suggests that the later generic manufacturers were in fact attempting to invalidate the patents. (*See, e.g.*, Humana Am. Compl. ¶ 384 (explaining how Dr. Reddy's initiated IPR to invalidate Celgene's method of treatment patents); *id.* ¶¶ 358–60, 391–93, 401, 411–13, 447–49, 471–72, 485–87, 501, 508–10, 515–17, 523–25, 529–31, 533 & 536–38). As such, this argument is unavailing.

Nevertheless, even if the Court were to credit the Insurer Plaintiffs' theory regarding how other generics would have acted if not for the MFE clause, "it remains unpersuaded that this kind of settlement te[rm] is made unlawful by *Actavis*." *See Actos*, 2015 WL 5610752, at *16. As recounted above, the MFE clause permits Natco to enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement, if a later (non-settling) generic is successful in invalidating Celgene's unexpired patents. (Humana Am. Compl. ¶¶ 432–33). "The practical effect of the [MFE] clause[] is thus to increase competition in the event that other generics entered the market." *Actos*, 2015 WL 5610752, at *15. As the court in *Actos* noted, it is difficult to view such a provision as a "payment" from Celgene because if triggered, Natco would only be compensated through the market when it began selling its generic product. *Id.* "An acceleration clause by its plain te[rm]s merely affects the date of entry into the market—a date that can be

lawfully agreed upon by the parties settling a patent infringement suit." *Id.* at *16. "The mere possibility that the absence of an acceleration clause may result in more diverse generic competition is insufficient for [p]laintiffs to plausibly state a reverse payment claim here. *Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Id; see also King Drug*, 791 F.3d at 408–09 ("*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible.").

Finally, the Insurer Plaintiffs point out that other courts have found that at the motion to dismiss stage an acceleration clause could plausibly be proven to constitute value transferred from a brand manufacturer to a generic manufacturer as part of an alleged reverse payment because it deterred later generics from trying to obtain an earlier entry date. (Opp. Br. at 20 n.68 & 69); *see, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 333–34 (D.R.I. 2017) (stating that while "[i]t may be that with more factual and expert discovery, the . . . [d]efendants can establish that there were no anticompetitive effects, or that . . . the 'challenged payment was justified by some pr[o]competitive objective[,]' . . . at this juncture, the [c]ourt is not prepared to hold that an acceleration clause like the one [here] may never be cognizable as a component of a complex settlement agreement amounting to a large and unjustified reverse payment" since it was plausible that the acceleration clause disincentivized other generics from entering the market earlier); *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 610 (N.D. Cal. 2020) (finding acceleration clause could plausibly produce anticompetitive effects by disincentivizing other generics from entering the market earlier but noting that it would be closer if the court was only dealing with an acceleration clause). However, unlike in *Loestrin* and *Staley* here, the Insurer Plaintiffs' own allegations, as described above, squarely undermine any possibility that the MFE clause operated as a reverse

payment because it disincentivized later generics from continuing to challenge Celgene's patents. As such, the Insurer Plaintiffs' reliance on these cases is unavailing. As such, the MFE clause in the Celgene-Natco settlement agreement in this case does not provide a basis for a claim within the meaning of *Actavis*.

In sum, the Court finds that neither the (i) volume limited, royalty free license nor (ii) the MFE clause plausibly amount to a reverse payment from Celgene to Natco within the meaning of *Actavis*. Because neither of those provisions can amount to a reverse payment on its own, they also cannot amount to a reverse payment when considered in combination. In fact, the Insurer Plaintiffs provide no allegations or arguments to explain how the volume limited, royalty free license and MFE clause could amount to a reverse payment when considered in combination, even if neither provision amounts to a reverse payment on its own. Accordingly, insofar as the Insurer Plaintiffs allege that the Celgene Defendants violated Section 1 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Natco, those allegations cannot proceed as pled. Likewise, insofar as the Insurer Plaintiffs allege that Defendants violated Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Natco, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

b. The Insurer Plaintiffs' Market Allocation Theory

The Insurer Plaintiffs also allege that, separate and apart from their reverse payment theory, the volume limits under the Celgene-Natco agreement amounted to an unlawful market allocation between Celgene and Natco. (Humana Am. Compl. ¶¶ 418 & 435–44). More specifically, the Insurer Plaintiffs contend that from when the settlement agreement "was reached in late 2015 and until early 2022, Natco (and later Teva) agreed to delay coming to market with any generic

lenalidomide, thereby allocating the entire lenalidomide market to Celgene and BMS until early 2022." (Opp. Br. at 22). The Insurer Plaintiffs also point out that the parties also agreed that, starting in March 2022, Natco and Teva would be allocated a small number of generic lenalidomide sales. (*Id.*). According to the Insurer Plaintiffs, "[t]his market allocation eliminated the incentive for Natco to compete on price (*i.e.*, to increase volume) to ensure that prices will remain supracompetitive even after generic entry." (*Id.*).[64]

As stated above, Section 1 of the Sherman Act declares as illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. Section 1 is interpreted to outlaw "unreasonable restraints" on trade. *Ohio v. Am. Express Co.*, 585 U.S. 529, 540 (2018) (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)) (formatting modified). To plead a claim under Section 1, a plaintiff must allege: (i) the existence of an agreement; and (ii) that the agreement unreasonably restrains trade. *See Am. Needle, Inc. v. NFL*, 560 U.S. 183, 190 (2010) (citations omitted). When assessing whether a particular restraint inhibits competition, courts apply three categories of analysis: per se, quick-look, and rule of reason. *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop., Inc.*, 89 F.4th 430, 438–39 (3d Cir. 2023). Per se analysis is applied when a "practice facially appears to be one that would always or almost always tend to restrict competition and decrease output," such as horizontal price fixing and output limitations. *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 100 (1984); *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 336 (3d Cir. 2018). Market allocation agreements, are "classic examples" of per se Section 1 violations. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972). "The essence of a market allocation violation, [] is that competitors apportion the market among themselves and

[64] The MSP Plaintiffs do not allege that the Celgene-Natco agreement amounted to an illegal market allocation. (*See generally* MSP SAC; Tr. of Aug. 18, 2023 Oral Arg. at 258:15–24).

cease competing in another's territory or for another's customers." *In re Ins. Brokerage Antitrust Litig.*, No. 04-5184, 2007 WL 1100449, at *10 (D.N.J. Apr. 5, 2007) (internal quotation marks and citation omitted). The quick-look approach, by contrast, is an intermediate standard that asks whether an "observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect." *Winn-Dixie Stores, Inc.*, 89 F.4th at 438–39 (quoting *Cal. Dental Ass'n v. FTC.*, 526 U.S. 756, 770 (1999)). If legitimate, procompetitive justifications for facially anticompetitive behavior are found, then rule of reason analysis may be necessary. *Avaya, Inc. v. Telecom Labs, Inc.*, No. 06-2490, 2009 WL 2928927, at *4, *10 (D.N.J. Sept. 9, 2009). Under the "rule of reason," the party seeking to impose liability must initially provide evidence of the anticompetitive nature of a defendant's conduct. *Mylan Pharm.*, 838 F.3d at 438. Once established, the defendant then has the burden of proffering nonpretextual procompetitive justifications for its conduct. *See id.* And "[t]he plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Id*. (internal quotation marks omitted).

Here, in addition to alleging that the Celgene-Natco agreement amounted to a reverse payment under *Actavis*, the Insurer Plaintiffs also separately allege that the Celgene-Natco agreement amounted to an illegal market allocation between Celgene and Natco in violation of Section 1 of the Sherman Act. (Opp. Br. at 21 ("Decades of antitrust jurisprudence holds that agreements between competitors to allocate a market, whether by output restriction or by market division, violate Sherman Act § 1"); Humana Am. Compl. ¶¶ 418 & 435–44). The Insurer Plaintiffs concede that per se treatment is not appropriate here to evaluate the legality of the Celgene-Natco settlement agreement under their market allocation theory. Rather, they seek to challenge the Celgene-Natco agreement as an improper market allocation agreement that raises

anticompetitive concerns under the rule of reason.[65] They assert that when courts have dismissed horizontal market allocation claims post-*Actavis*, it is because the plaintiff argued that a settlement agreement should be deemed unlawful *per se* rather than evaluated under a rule-of-reason standard. (Opp. Br. at 25). And because the Insurer Plaintiffs do not argue that the settlement agreement should be deemed unlawful *per se*, they contend that their market allocation theory should not be dismissed. (*Id.*). The Celgene Defendants argue that the Insurer Plaintiffs' market allocation claim fails because settlements of patent litigation are not subject to antitrust scrutiny outside of the limited exception recognized by the Supreme Court in *Actavis*, which stated that reverse payment settlement agreements, specifically, may be subject to antitrust scrutiny. (Mov. Br. at 42–43). Further, the Celgene Defendants argue that the Insurer Plaintiffs' market allocation theory fails because volume-limited licenses are a valid exercise of patent rights. More specifically, they contend that just as a patentee may decide whether and to whom to license its patent, so too may it "by license restrict production of the licensee to a specified quantity, at a specified place." (Mov. Br. at 40 (citing *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118, 1151 n.17 (D.N.J. 1976)). For the reasons set forth below, the Court agrees with the Celgene Defendants.

"The Supreme Court has long recognized that certain exercises of patent rights are lawful despite the Sherman Act's dictates." *Fed. Trade Comm'n v. Endo Pharms. Inc.*, 82 F.4th 1196,

[65] Notably, in *Actavis*, the Supreme Court stated that the legality of reverse payments should be evaluated under the rule of reason. *Actavis*, 570 U.S. at 159. The *Actavis* Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. *King Drug*, 791 F.3d at 412. First, it stated that the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. *Actavis*, 570 U.S. at 154–56. Second, it explained that the burden then shifts to the defendant to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 156. Finally, it explained that the plaintiff will have the opportunity to rebut the defendant's explanation. *King Drug*, 791 F.3d at 412. Here, in addition to alleging that the Celgene-Natco agreement amounted to a reverse payment under *Actavis*, the Insurer Plaintiffs also seek to challenge the Celgene-Natco agreement as an improper market allocation agreement that raises anticompetitive concerns under the rule of reason *separate and apart* from the standard promulgated by *Actavis* and its teachings on what constitutes an unlawful reverse payment settlement agreement.

1203–04 (D.C. Cir. 2023). For example, in *United States v. Gen. Elec. Co.*, 272 U.S. 476 (1926), the Supreme Court emphasized that the "owner of a patent may assign it to another and convey . . . the exclusive right to make, use, and vend the invention" as well as "grant a license to make, use, and vend articles under the specifications of his patent for any royalty, or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure." *Gen. Elec. Co.*, 272 U.S. at 489. In the same vein, the Supreme Court has acknowledged that patent owners can place conditions on a licensee's sale of the patented product, "provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 299 (1948) (quoting *Gen. Elec.*, 272 U.S. at 490).

As already recounted above, in *Actavis*, the Supreme Court again confronted the interplay between antitrust laws and patent laws in the context of reverse payment settlement agreements. There, as explained by the Seventh Circuit, the Supreme Court held that "one kind of settlement, in which the patent holder pays the potential entrant to defer entry, could be unlawful when the payment exceeds any reasonable estimate of the costs of litigation and is best understood as a portion of the spoils from a market-division agreement." *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 714 (7th Cir. 2022). In so holding, the Supreme Court emphasized that when a complaint alleges that a patent holder has violated the antitrust laws, courts must strike a balance "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act." *Actavis*, 570 U.S. at 148 (quoting *Line Material Co.*, 333 U.S. at 310) (internal quotation marks omitted). And the Supreme Court further emphasized that "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question." *Id.* at 147. Nevertheless, as the D.C. Circuit in *Endo* recently recognized,

"while *Actavis* held that the unexplained 'reverse payment' at issue in that case was subject to antitrust scrutiny, it did not disturb the long-standing principle that a single patentee may set conditions in granting a single licensee the right to use its valid patents." *Endo*, 82 F.4th at 1204.

Multiple courts have suggested that a plaintiff cannot challenge a patent settlement agreement as an unlawful market allocation outside of alleging that the agreement amounts to a reverse payment under *Actavis*. For example, in *In re Novartis & Par Antitrust Litig.*, No. 18-11835, 2019 WL 3841711, at *4 (S.D.N.Y. Aug. 15, 2019), the court rejected the plaintiffs' attempt to challenge a patent settlement agreement as a market division that was per se illegal under Section 1 of the Sherman Act. In so holding, the court emphasized that "[b]ecause the alleged conduct unfolded in the context of and depended on an intricate statutory regime, the Supreme Court's teaching on that regime applies [i.e. the *Actavis* standard], and not general principles of market allocation agreements." *Id*. As such, the court concluded that to analyze the legality of the patent settlement agreement in that case the "case law uniformly supports the application of *Actavis* and the rule of reason approach" specifically. *Id*. Likewise, in *Humira*, after the court decided that the rule of reason, rather than the per se test, applied to assess the plaintiffs' market allocation claim challenging a patent settlement agreement, it specifically applied *Actavis* and its teachings on what constitutes a reverse payment settlement agreement to determine whether the plaintiffs had plausibly alleged that the agreement was unlawful. *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 838–39 (N.D. Ill. 2020), *aff'd sub nom. Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022). That decision was affirmed on appeal. And in affirming the district court, the Seventh Circuit explained that if settlement agreements that carve the market between the brand manufacturer and generic manufacture could be classified as cartels, then all settlements of patent cases would violate the

Sherman Act. *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 714 (7th Cir. 2022). However, the Seventh Circuit noted that this could not be true since the Supreme Court clarified that normal settlements of patent litigation are lawful. *Id.* The court reasoned that under *Actavis* only one kind of settlement could be unlawful—a settlement that involves a reverse payment. *Id.* Together, these decisions suggest that a plaintiff cannot challenge a patent settlement agreement as an unlawful market allocation outside of alleging that the agreement amounts to a reverse payment under *Actavis*. *See also AbbVie Inc.*, 976 F.3d at 359 ("As to AbbVie's settlement with Teva, the District Court erred in concluding it was procompetitive as a matter of law. Granted, the District Court was right that under *Actavis*, 'an agreement does not run afoul of the antitrust laws' if it simply allows a generic company to enter a market before patent expiration. And it was reasonable for the Court to think this exception reflects the Supreme Court's view that such agreements are so often procompetitive they should be legal per se. Still, the exception applies *only if* a patentee does not 'pay[ ] the challenger to stay out [before patent expiration]") (emphasis added); *see also Actos*, 2015 WL 5610752, at *14 ("[A] reading of *Actavis* that would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment would ignore the limiting principles set forth in the decision, and subject virtually *any* settlement to antitrust scrutiny-a result the Court could not have intended.") And as explained above, the Insurer Plaintiffs have failed to plead that the Celgene-Natco settlement agreement amounted to a reverse payment under *Actavis*.

The District Court of Delaware's decision in *Sensipar* is also instructive on this point. In *Sensipar*, in addition to raising a reverse payment theory, the plaintiffs alleged that a settlement agreement between Amgen and Teva also violated Section 1 of the Sherman Act under a market allocation theory. There, the court reasoned that to the extent the plaintiffs alleged that the Amgen-

Teva agreement reduced competition by removing Teva from the market, the plaintiffs' market allocation theory essentially amounted to a pay-for-delay theory and hence depended upon an allegation of an unlawful reverse payment governed by the rule of reason test under *Actavis*. *Sensipar*, 2022 WL 736250, at *10. The court saw no good reason to treat the plaintiffs' market allocation theory as a stand-alone claim where all of the allegations supporting that theory would be included as part of a reverse payment theory. *Id.* The Court finds the present facts analogous. More specifically, as described above, pursuant to their market allocation theory, the Insurer Plaintiffs allege that the Celgene-Natco agreement reduced competition by removing Natco from the market. (Tr. of Aug. 18, 2023 Oral Arg. at 250:15–20). As such, like in *Sensipar*, here, the Insurer Plaintiffs' market allocation theory essentially amounts to a pay-for-delay theory and hence depends upon an allegation of an unlawful reverse payment governed by the rule of reason test under *Actavis*. *Sensipar*, 2022 WL 736250, at *10. In fact, the Insurer Plaintiffs indicated that they did not have any additional allegations to support their market allocation theory that were not already included as part of their reverse payment theory. (Tr. of Aug. 18, 2023 Oral Arg. at 254:9–22). The court sees no good reason to treat the Insurer Plaintiffs' market allocation theory as a stand-alone claim. *Sensipar*, 2022 WL 736250, at *10. And as explained above, the Insurer Plaintiffs have failed to plead that the Celgene-Natco settlement agreement amounted to reverse payment under *Actavis*.

Nevertheless, even if the Insurer Plaintiffs could challenge the Celgene-Natco settlement agreement outside of the parameters set forth in *Actavis* and its teachings on what constitutes an unlawful reverse payment settlement agreement, any such claim fails. The D.C. Circuit's decision in *Fed. Trade Comm'n v. Endo Pharms. Inc.*, 82 F.4th 1196 (D.C. Cir. 2023) is instructive in the Court's analysis of this issue. In *Endo*, the D.C. Circuit considered whether the FTC had plausibly

alleged that an agreement entered into between two companies violated Sections 1 and 2 of the Sherman Act by creating an impermissibly anticompetitive exclusive licensing arrangement. *Endo*, 82 F.4th at 1200–02. Notably, the plaintiffs in that case did not allege that there was a reverse payment settlement. *Fed. Trade Comm'n v. Endo Pharms. Inc.*, 596 F. Supp. 3d 115, 122 n.3 (D.D.C. 2022), *aff'd*, 82 F.4th 1196 (D.C. Cir. 2023). The court concluded that the FTC had failed to state a claim under the Sherman Act because the FTC failed to distinguish the agreement from a standard exclusive license and did not point to any aspects of the agreement that might further justify antitrust scrutiny. *Endo*, 82 F.4th at 1206. Nevertheless, the court noted that "[i]n a future case, the Commission is free to plead that a licensing agreement results in unjustifiable competitive harms, so long as it explains how those harms exceed what the Patent Act and settled precedent permit." *Id.* As such, to determine whether the Insurer Plaintiffs have adequately pled that the Celgene-Natco settlement agreement resulted in unjustifiable competitive harms in violation of the Sherman Act outside of alleging that the agreement amounts to a reverse payment under *Actavis*, the Court will examine whether they have pled any harms that exceed what the Patent Act and settled precedent permit. The Court finds that they have not. [66]

[66] The Insurer Plaintiffs attempt to distinguish *Endo* in part based on the fact that the validity, infringement, and enforceability of the patents in *Endo* were not disputed in the underlying lawsuit. (D.E. No. 243 at 2). As a result, they contend that unlike *Actavis* and this case, there was no fair inference that the settlement involved any exchange of consideration to avoid the risk of a finding of patent invalidation or noninfringement. (*Id.*). To be sure, in *Actavis* the Supreme Court held that reverse payments "can sometimes unreasonably diminish competition in violation of the antitrust laws" and noted that the "size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness" and a patentee's market power, "all without forcing a court to conduct a detailed exploration of the patent itself." *Actavis*, 570 U.S. at 141, 157–58. Nevertheless, as already described above, the Court finds that the Insurer Plaintiffs have failed to plausibly allege that Celgene transferred to Natco any "unusual" consideration to avoid the risk of a finding of patent invalidation or noninfringement. *See Endo*, 82 F.4th at 1206. As such, their attempt to distinguish *Endo* is unavailing.

Further, to the extent the Insurer Plaintiffs attempt to argue that any patent settlement may be subject to antitrust scrutiny as an unlawful market allocation when the validity, infringement, and enforceability of the patents in the underlying lawsuit are in dispute, the Court disagrees. Every patent lawsuit carries the risk of a finding of patent invalidation or noninfringement. If such were not the case, patent holders would seldom be motivated to settle lawsuits against alleged infringers. As such, the mere fact that the validity, infringement, and enforceability of the patents in an underlying lawsuit may have been in dispute is not sufficient to subject any resulting settlement agreement to antitrust scrutiny. Otherwise, nearly all settlements of patent cases would violate the Sherman Act. *AbbVie Inc.*, 42

Here, Celgene licensed Natco to enter the market with generic lenalidomide before patent expiry, first at limited volumes and then without restriction. (Humana Am. Compl. ¶ 368). Beyond arguing (unsuccessfully) that the Celgene-Natco agreement amounted to an unlawful reverse payment under *Actavis*, the Insurer Plaintiffs have failed to plead that the agreement resulted in unjustifiable competitive harms, that "exceed what the Patent Act and settled precedent permit." *Endo*, 82 F.4th at 1206. The Patent Act grants patentees a twenty-year "right to exclude others from making, using, offering for sale, or selling the[ir] invention," 35 U.S.C. § 154(a)(1), and the ability to "grant and convey an exclusive right under [their] application for patent, or patents, to the whole or any specified part of the United States." *Id.* § 261. Further, as stated above, "[t]he Supreme Court has long recognized that certain exercises of patent rights are lawful despite the Sherman Act's dictates." *Endo*, 82 F.4th at 1203–04. In fact, the Supreme Court has acknowledged that patent owners can place conditions on a licensee's sale of the patented product, "provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly." *Line Material Co.*, 333 U.S. at 299 (internal quotation marks omitted). As the Celgene Defendants point out (Mov. Br. at 39–40) and as a leading antitrust treatise has recognized, "it seems almost inherent in the concept of the sale of [the] license . . . that the [licensor] can [license] as little or as much as it pleases." Areeda & Hovenkamp, *An Analysis of Antitrust Principles and Their Applications* ¶ 2042 (4th & 5th eds. 2013–2020).[67]

F.4th at 714. However, as the Seventh Circuit noted, this cannot be true since the Supreme Court clarified that normal settlements of patent litigation are lawful. *Id.*

[67] In their Opposition Brief, the Insurer Plaintiffs state that "[a]ntitrust treatises recognize 'fears of competitive harm grow' where 'the licensor is itself a manufacturer' and licenses to competitors." (Opp. Br. at 24). Nevertheless, as the Celgene Defendants point out, that treatise also acknowledges that "courts have generally been tolerant of horizontal output limitations in intellectual property licenses, at least when the restriction was imposed by the licensor on each licensee individually and there was no proof of an output limitation agreement among the licensees themselves." (Reply at 20–21 (citing Hovenkamp et al., *IP and Antitrust* § 32.01 (3d ed.)). Here, while the Insurer Plaintiffs allege that Celgene entered into multiple settlement agreements with generic manufacturers, in addition to

In fact, courts within this District have recognized that a patentee can lawfully "by license restrict production of the licensee to a specified quantity, at a specified place," without running afoul of the antitrust laws. *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118, 1151 n.17 (D.N.J. 1976) (quoting *United States v. E.I. DuPont de Nemours & Co.*, 118 F. Supp. 41, 226 (D. Del. 1953), *aff'd on other grounds*, 351 U.S. 377 (1956)). For example, in *CIBA* the court considered the legality of a licensing agreement between a patent holder and another company. There CIBA, the holder of patents on a drug known as HCT, granted Abbott a limited license to make, use, and vend HCT in specialty form only. *CIBA*, 508 F. Supp. at 1149. Under the terms of the license, "Abbott could not sell bulk HCT without being subject to a claim for infringement." *Id.* The court rejected the government's attempt to classify the agreement as an unlawful restraint of trade under Section 1. Rather, the court noted that the license "opened up competition in an area in which CIBA had the legal right to shut off all competition." *Id.* at 1151. It noted that "[t]o say that CIBA 'restrained competition' by not licensing Abbott in as unlimited a fashion as was possible is to impose a duty upon the patentee that simply is not justifiable." *Id.*; *see also Q-Tips, Inc. v. Johnson & Johnson*, 109 F. Supp. 657, 660–61 (D.N.J.1951), *aff'd*, 206 F.2d 144 (3d Cir. 1953) (upholding quantity limitations); *United States v. E.I. DuPont de Nemours & Co.*, 118 F. Supp. 41, 226 (D. Del. 1953), *aff'd on other grounds*, 351 U.S. 377 (1956) (approving a provision in a license agreement that the licensee could make up to a stipulated quantity of cellophane at one royalty rate, but must pay a higher royalty rate on any excess); *see also Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1578 (Fed. Cir. 1990).[68]

Natco, under volume limited licenses (Humana Am. Compl. ¶¶ 376–417 & 430), the Insurer Plaintiffs do not plead that there was any output limitation agreement among those generic manufacturers themselves.

[68] The Insurer Plaintiffs' cited case law does not compel this Court to reach a contrary conclusion. (Opp. Br. at 21–22 nn.72 & 73.). To start, in order to support their claim that the Celgene-Natco agreement amounted to an unlawful market allocation, the Insurer Plaintiffs cite to the Supreme Court's decision in *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). In *Palmer*, the Supreme Court found that it was a per se violation of Section 1 for BRG to

To be sure, as the Supreme Court in *Actavis* emphasized, "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question." *Actavis*, 540 U.S. at 147. However, the Insurer Plaintiffs' Amended Complaint lacks allegations establishing that the Celgene-Natco agreement "created anticompetitive effects greater than that authorized by settled law and precedent." *Endo*, 82 F.4th at 1206. Neither precedent nor the Insurer Plaintiffs' allegations permit this Court to conclude that the Celgene-Natco license differs from a license that restricts production of the licensee to a specified quantity, which courts in this district have deemed lawful despite the Sherman Act's dictates. *CIBA*, 508 F. Supp. at 1149–51; *Q-Tips, Inc.*, 109 F. Supp. at 660–61; *see also Gen. Elec. Co.*, 272 U.S. at 489; *DuPont*, 118 F. Supp. at 226. While the Insurer Plaintiffs contend that the Celgene-Natco agreement had the effect of unlawfully

promise not to provide bar review courses outside of Georgia in return for a promise from its competitor to not provide bar review courses inside of Georgia. *Palmer*, 498 U.S. at 47. The Supreme Court noted that the exclusive licensing agreement in that case was merely a pretext for a noncompete agreement between two competitors, because the parties in *Palmer* did not require one another's intellectual property to participate in the market for bar preparation courses. In contrast, here, Natco's ability to enter the lenalidomide market was contingent on its ability to use or overcome Celgene's patents. *Endo*, 82 F.4th at 1205 n.1. The other cases that the Insurer Plaintiffs cite to support their market allocation theory either applied outside of the patent licensing context and/or applied a per se standard to evaluate the legality of the restraint at issue, which the Insurer Plaintiffs concede is not applicable here. *See e.g., U.S. v. Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972) (finding territorial allocations per se unlawful); *N. Pac. Ry. Co. v. U.S.*, 356 U.S. 1, 5 (1958) (finding that leases for land with preferential routing clauses were per se unlawful restraints of trade); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1242 (3d Cir. 1975) (evaluating whether franchising practices were unlawful restraints of trade); *In re Sulfuric Acid Antitrust Litig.*, 743 F. Supp. 2d 827, 869 (N.D. Ill. 2010) (analyzing whether agreements outside of intellectual property licenses to reduce output and fix price of sulfuric acid were per se unlawful restraints of trade); *U.S. v. Sargent Elec. Co.*, 785 F.2d 1123, 1127 (3d Cir. 1986) (analyzing whether bid rigging arrangements where per se illegal); *In re Ins. Brokerage Antitrust Litig.*, MDL No. 1663, 2007 WL 1100449, at *10 (D.N.J. Apr. 5, 2007) (analyzing whether defendants engaged in combination to suppress competition in sale of insurance under per se standard); *In re Magnesium Oxide Antitrust Litig.*, No. 10-5943, 2011 WL 5008090, at *16 (D.N.J. Oct. 20, 2011). (evaluating whether conspiracy to fix prices and allocate shares of domestic magnesium oxide market were lawful under per se standard). As such, the Insurer Plaintiffs' reliance on these cases is unavailing.

Likewise, to the extent the Insurer Plaintiffs attempt to analogize this case to *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952) and *United States v. Singer Mfg. Co.*, 374 U.S. 174, 83 S. Ct. 1773, 10 L. Ed. 2d 823 (1963) (Tr. of Aug. 18, 2023 Oral Arg. at 139:25–140:2), those cases are also distinguishable from the facts of this case. *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 380 (1952) (invalidating a scheme in which multiple patent holders "pool[ed] their patents" to "fix prices on . . . products for themselves and their licensees"); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 190–96 (1963) (disapproving of a concerted agreement among multiple patent holders with potentially conflicting patents to unite instead of litigating patent infringement claims among themselves and to grant the company with the greatest prosecuting power the right to prosecute the patents against competitors on all three companies' behalf, thereby giving each company more power than it had alone and extending the companies' activities "beyond the limits of the patent monopoly.").

allocating the relevant market for Revlimid and its generic equivalents, *Actavis* "did not disturb the long-standing principle that a single patentee may set conditions in granting a single licensee the right to use its valid patents." *Endo*, 82 F.4th at 1204.[69] As the Seventh Circuit pointed out in *AbbVie*, if settlement agreements that carve the market between the brand manufacturer and generic manufacture could be classified as cartels, "then all settlements of patent cases would violate the Sherman Act." *AbbVie Inc.*, 42 F.4th at 714. The Court declines to expand the contours of the Sherman Act in this manner to accommodate the Insurer Plaintiffs' theory in the absence of precedent that states it should do so. As such, to the extent that the Insurer Plaintiffs' challenge the Celgene-Natco license as an unlawful market allocation in violation of the Sherman Act, any such theory cannot proceed and must be dismissed.[70]

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[69] To be sure, in *King Drug*, the Third Circuit noted that "the fact that a patent holder may generally have the right to grant licenses, exclusive or otherwise, does not mean it also has the right to give a challenger a license along with a . . . promise not to compete—in order to induce the challenger to respect its patent and quit [the competitor's] patent invalidity or noninfringement claim without any antitrust scrutiny." *King Drug*, 791 F.3d at 406–07 (internal quotation and citation omitted). While the Third Circuit was careful to make any statement about patent licensing more generally, it noted that "the fact that the Patent Act expressly authorizes licensing does not necessarily mean it also authorizes reverse payments to prevent generic competition." *Id.* at 407. Here, as discussed, the Insurer Plaintiffs have failed to plead that the Celgene-Natco agreement amounted to a reverse payment. And while the Court acknowledges that patent licenses cannot avoid antitrust scrutiny when they are used in anticompetitive ways, here the Insurer Plaintiffs' Amended Complaint lacks allegations establishing that the Celgene-Natco agreement "created anticompetitive effects greater than that authorized by settled law and precedent." *Endo*, 82 F.4th at 1206.

[70] The Insurer Plaintiffs cite to *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 597–98 (N.D. Cal. 2020), for the proposition that provisions in a patent settlement agreement can be challenged under a rule of reason analysis separate from *Actavis*. (Opp. Br. at 25 n.89). The Court, however, finds *Staley* distinguishable. There, the court found that it was plausible that a "no-generics" restraint provision in an agreement between Gilead and generic manufacturers was anticompetitive under the rule of reason outside of *Actavis*. *Gilead*, 446 F. Supp. 3d at 597–605. In that case the "no-generics" restraint provision had the effect of preventing generic manufacturers from selling drug formulations with generic versions of the drug even after Gilead's patents on that drug expired. *Id.* at 595–98. Here, however, the Insurer Plaintiffs do not allege that Celgene attempted to prevent Natco from marketing generic versions of lenalidomide even after Celgene's patents expired. And as described above, beyond arguing that the Celgene-Natco agreement amounted to an unlawful reverse payment under *Actavis*, the Insurer Plaintiffs have failed to plead that the agreement results in unjustifiable competitive harms that "exceed what the Patent Act and settled precedent permit." *Endo*, 82 F.4th at 1206. As such, *Staley* is distinguishable.

The Insurer Plaintiffs also cite to the court's decision in *Xyrem* for the proposition that provisions in a patent settlement agreement can be challenged under a rule of reason analysis separate from *Actavis*. (Opp. Br. at 25 n.89). As the Insurer Plaintiffs point out, the court in *Xyrem* appears to have analyzed a market allocation theory claim separate and apart from *Actavis*. More specifically, the court found that Jazz's volume-limited licenses with generic defendants were plausibly anticompetitive market allocations that reduced output and raised prices. *Xyrem*, 555 F. Supp. 3d at 870. And it appears to have made this finding, *in addition* to its finding that the plaintiffs plausibly alleged a reverse payment agreement under *Actavis*. *Id.* at 863–65, 870. Nevertheless, as recounted above, multiple courts

a. The MSP Plaintiffs' Reverse Payment Allegations

As recounted above, the joint Opposition Brief filed by the Insurer Plaintiffs and the MSP Plaintiffs on November 15, 2022 clearly provided that the MSP Plaintiffs had not alleged a viable reverse payment claim. (Opp. Br. at 3 ("[T]he complaints allege (***except for*** . . . ***MSP***) viable reverse payment claims.") (emphasis added)). Despite this clear concession, nearly a year later, on August 18, 2023, the MSP Plaintiffs informed the Court for the first time at oral argument that this concession in their brief was a mistake and clarified that they were in fact asserting a claim against Celgene under Section 2 of the Sherman Act for entering into an allegedly anticompetitive reverse payment settlement agreement with Natco. (Tr. of Aug. 18, 2023 Oral Arg. at 122:6–126:18). Unlike the Insurer Plaintiffs, the MSP Plaintiffs only allege that the settlement agreement between Celgene and Natco constituted an unlawful reverse payment because it provided Natco with a volume limited license. (MSP SAC ¶ 380; Tr. of Aug. 18, 2023 Oral Arg. at 125:11–14). According to the MSP Plaintiffs, the volume-limited nature of the license functions as a no authorized generic provision "because it restricts Celgene's ability to launch its own generic—thereby establishing a *quid pro quo* relationship where the generic [] (i.e. Natco) decreases competition in the generic brand market (by eliminating Celgene's ability to launch its own generic brand) in exchange for the generic brand (i.e. Natco) agreeing to stay off the market for a certain amount of years." (MSP SAC ¶ 380). The MSP Plaintiffs raise no allegations regarding the royalty-free nature of the license or the MFE clause to support their reverse payment allegations as to the Celgene-Natco agreement. (Tr. of Aug. 18, 2023 Oral Arg. at 125:11–19).

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have suggested that patent settlement agreements can only be challenged as reverse payments under the rule of reason as applied in *Actavis*, specifically. *Novartis*, 2019 WL 3841711, at *4; *Humira* 465 F. Supp. 3d at 838–42; *Sensipar*, 2022 WL 736250, at *10. And regardless, as stated above, the Insurer Plaintiffs' complaint lacks allegations establishing that the Celgene-Natco agreement "created anticompetitive effects greater than that authorized by settled law and precedent." *Endo*, 82 F.4th at 1206. As such, the Court will not rely on *Xyrem* in reaching a contrary conclusion.

Even though the MSP Plaintiffs essentially waived any such claim (Opp. Br. at 3), the Court nevertheless relies on the same reasoning it employed in Section III(C)(iii)(a) (*supra* at 143–162) and finds that the MSP Plaintiffs have failed to plausibly allege that the volume limited nature of the Celgene-Natco license amounted to a reverse payment. Accordingly, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Natco, that component of the overall scheme, on its own, cannot support a claim under Section 2 of the Sherman Act.

At oral argument, the MSP Plaintiffs also clarified for the first time that they are additionally alleging that Celgene entered into anticompetitive reverse payment settlement agreements with Barr, Lannett, Dr. Reddy's, Zydus, and Cipla. (Tr. of Aug. 18, 2023 Oral Arg. at 223:22–224:2 (citing MSP SAC ¶¶ 39, 47, 214, 356–60, 366–80, 387, 392, 405, 411 & 418)). None of these conclusory allegations plausibly allege a reverse payment under *Actavis*.

To start, the MSP Plaintiffs allege that in September 2006 Barr filed an ANDA with the FDA for a generic version of Thalomid. (MSP SAC ¶ 346). As a result, Celgene filed a lawsuit against Barr in 2007. (*Id.* ¶ 347). On May 5, 2010, the parties settled. (*Id.* ¶ 356). According to the MSP Plaintiffs, the settlement's terms "likely . . . included a reverse payment agreement from Celgene to Barr." (*Id.* ¶ 357). The MSP Plaintiffs' Second Amended Complaint is entirely devoid of any allegations as to why the agreement amounted to an anticompetitive reverse payment to Barr. In their Moving Brief, the Celgene Defendants pointed out that although the MSP Plaintiffs speculate that the termination of Celgene's patent suit with Barr may have included a reverse payment from Celgene, the public docket shows unambiguously that Barr simply withdrew its application to market the product, and so Celgene's patent case was dismissed without settlement. (Mov. Br. at 25–26 (citing *Celgene Corp. v. Barr Labs.*, No. 07-0286 (D.N.J.), (D.E. No. 157)

(May 13, 2010), (D.E. No. 160) (May 21, 2010))). The MSP Plaintiffs provided no response in their Opposition Brief to oppose this argument. Nor did they set forth any argument to explain how they had adequately alleged a reverse payment with respect to any agreement entered into between Celgene and Barr. (*See generally* Opp. Br.). As such, the Court finds any such argument by the MSP Plaintiffs waived. *Market v. PNC Fin. Servs. Grp.*, 828 F. Supp. 2d 765, 773 (E.D. Pa. 2011) ("Where an issue of fact or law is raised in an opening brief, but it is uncontested in the opposition brief, the issue is considered waived or abandoned by the non-movant in regard to the contested issue."). Regardless, the MSP Plaintiffs' conclusory allegation that the alleged Celgene-Barr settlement agreement "likely . . . included a reverse payment agreement from Celgene to Barr" is plainly insufficient to plead a "payment" made in "reverse" under *Actavis*. (MSP SAC ¶ 357). Accordingly, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Barr, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

Next, the MSP Plaintiffs allege that Lannett sued Celgene, asserting violations of the Sherman Act based on Celgene's refusals to provide Lannett with samples of Thalomid. (*Id.* ¶¶ 208 & 211). According to the MSP Plaintiffs, Lannett and Celgene entered into a confidential settlement in 2011 that "contained anticompetitive terms, such as a promise to delay submission of [an] ANDA" for Thalomid. (*Id.* ¶¶ 212–14). Likewise, the MSP Plaintiffs allege that after Lannett filed its ANDA to gain approval to market its generic version of Thalomid, Celgene filed suit against Lannett in 2015. (*Id.* ¶¶ 361–62). They allege that Celgene and Lannett entered into a settlement in 2017, which delayed the entry date of Lannett's thalidomide product. (*Id.* ¶¶ 365–66). In their Moving Brief, the Celgene Defendants argued that any claim as to "delayed" entry

of a "Lannett generic Thalomid" fails because even with a license to Celgene's patents that began in 2019, which Lannett obtained after its settlement with Celgene, Lannett never launched a generic Thalomid product. (Mov. Br. at 27; MSP SAC ¶¶ 215 & 366). The MSP Plaintiffs again provided no response in their Opposition Brief to oppose this argument, nor did they set forth any argument to explain how they adequately alleged that any agreement entered into between Celgene and Lannett was anticompetitive. (*See generally* Opp. Br.). As such, the Court finds any such argument by the MSP Plaintiffs waived. *Market*, 828 F. Supp. 2d at 773. Regardless, the MSP Plaintiffs' conclusory allegations that the alleged 2011 Celgene-Lannett settlement agreement "contained anticompetitive terms" (MSP SAC ¶ 214), and that the 2017 settlement agreement delayed the entry date of Lannett's thalidomide product (*id.* ¶ 366) are plainly insufficient to plead a reverse payment under *Actavis*. Accordingly, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Lannett, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.[71]

The MSP Plaintiffs also appear to allege that Celgene entered into anticompetitive reverse payment settlement agreements with Dr. Reddy's and Cipla to end what were then-pending patent infringement lawsuits against those generic competitors. (Tr. of Aug. 18, 2023 Oral Arg. at 223:22–224:2; MSP SAC ¶¶ 387, 392, 397 & 427). The MSP Plaintiffs allege that Celgene's agreements with Dr. Reddy's and Cipla amounted to reverse payments because both of the

[71] At oral argument, the MSP Plaintiffs clarified that they are pursuing stand-alone Thalomid claims based *only* on Celgene's conduct in refusing to sell samples of Thalomid to generic manufacturers and in providing co-pay assistance for that drug. (Tr. of Sept. 8, 2023 Oral Arg. at 89:2–11). They at no point, however, indicated that they were pursuing stand-alone Thalomid claims based on Celgene's conduct in entering into anticompetitive reverse payment settlement agreements. Nevertheless, they still purport to challenge agreements between Celgene and Barr and Celgene and Lannett even though those parties were litigating over Thalomid. (Tr. of Aug. 18, 2023 Oral Arg. at 223:22–224:2). This is an additional reason why the Court finds that the MSP Plaintiffs have waived any argument that they adequately alleged a reverse payment with respect to any agreement entered into by Celgene and Lannett and Celgene and Barr.

agreements contained volume limited licenses which protected the vast majority of Celgene's Revlimid prescription base from generic competition and gave Dr. Reddy's and Cipla little to no incentive to lower their price because they cannot gain additional market share and because those settlements likely included agreements not to launch an authorized generic. (MSP SAC ¶¶ 387 & 427). In their Moving Brief, the Celgene Defendants indicated that it was their understanding that all of the Insurer Plaintiffs and MSP Plaintiffs had expressly disclaimed having any well-founded allegations with respect to the legality of any Celgene patent settlement apart from the Celgene-Natco settlement agreement. (Mov. Br. at 7–8 n.3).[72] Despite this clear assertion by the Celgene Defendants, the MSP Plaintiffs set forth no argument in their Opposition Brief to contest this understanding, nor did they set forth any argument to explain how they had adequately alleged a reverse payment with respect to any agreement entered into by Celgene and Dr. Reddy's and Celgene and Cipla. (*See generally* Opp. Br.). As such, the Court finds any such argument by the MSP Plaintiffs waived. *Market*, 828 F. Supp. 2d at 773. Nevertheless, to the extent that the MSP Plaintiffs challenge the volume-limited nature of the agreements entered into between Celgene and Dr. Reddy's and/or Cipla, the Court relies on the same reasoning it employed in Section III(C)(iii)(a) (*supra* at 143–162), and finds that the MSP Plaintiffs have failed to plausibly allege that the volume-limited nature of these agreements amounted to a reverse payment. Further, the MSP Plaintiffs assert that the agreement into which Celgene entered with Dr. Reddy's and Cipla amounted to reverse payments because under those agreements, "Celgene is likely restricted from

[72] While the Court acknowledges that in making this statement, the Celgene Defendants cited only to the Humana Amended Complaint and not the MSP Plaintiffs' Second Amended Complaint, the Celgene Defendants still referred to "Plaintiffs" collectively. (Mov. Br. at 7–8 n.3). And the MSP Plaintiffs even acknowledged at oral argument that they have largely been treated as one with the Insurer Plaintiffs. (Tr. of Sept. 8, 2023 Oral Arg. at 19:5–9). Nevertheless, the MSP Plaintiffs set forth no argument in their Opposition Brief to contest the Celgene Defendants' understanding and show that they were challenging as unlawful Celgene patent settlements other than the Celgene-Natco settlement. (*See generally* Opp. Br.).

launching its own generic through penalties in the event an authorized generic product is launched." (MSP SAC ¶¶ 387 & 427). Such speculative and conclusory allegations are plainly insufficient to plead a reverse payment under *Actavis*. As such, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into a reverse payment settlement agreement with Dr. Reddy's and/or Cipla, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

Next, the MSP Plaintiffs allege that Celgene settled a patent infringement action with Zydus on terms that "likely contained anticompetitive provisions amounting to a 'pay-for-delay' agreement." (*Id.* ¶¶ 405 & 411). As already noted, in their Moving Brief, the Celgene Defendants indicated that it was their understanding that the Insurer Plaintiffs and MSP Plaintiffs had expressly disclaimed having any well-founded allegations with respect to the legality of any Celgene patent settlement other than the Celgene-Natco agreement. (Mov. Br. at 7–8 n.3). Despite this clear assertion by the Celgene Defendants, the MSP Plaintiffs set forth no argument in their opposition brief to contest this understanding, nor did they set forth any argument to explain how they had adequately alleged a reverse payment with respect to any agreement entered into by Celgene and Zydus. (*See generally* Opp. Br.). As such, the Court finds any such argument by the MSP Plaintiffs waived. *Market*, 828 F. Supp. 2d at 773. Regardless, the MSP Plaintiffs' Second Amended Complaint is entirely devoid of any allegations as to why the agreement amounted to an anticompetitive reverse payment to Zydus. (*See generally* MSP SAC). Such conclusory allegations are insufficient to plead a reverse payment under *Actavis.* Accordingly, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into an anticompetitive reverse payment settlement agreement with Zydus, that component of the overall scheme cannot support a claim under Section 2 of the Sherman Act.

Finally, the MSP Plaintiffs' Second Amended Complaint also raises conclusory allegations that Celgene entered into anticompetitive reverse payment settlement agreements with Alvogen, Sun, Hetero, and Apotex. (MSP SAC ¶¶ 432, 436, 443, 460 & 468). More specifically, the MSP Plaintiffs allege that Celgene's agreements with Alvogen, Hetero, and Apotex "likely contained anticompetitive provisions amounting to a 'pay-for-delay' agreement." (*Id.* ¶¶ 436, 460 & 468). Further, the MSP Plaintiffs allege that the agreement Celgene entered into with Alvogen and Sun amounted to reverse payments because the agreements contained volume limited licenses that protected the vast majority of Celgene's Revlimid prescription base from generic competition and gave Alvogen and Sun little to no incentive to lower their price because they cannot gain additional market share. (MSP SAC ¶¶ 432 & 443). Further, the MSP Plaintiffs assert that under those agreements, "Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched." (*Id.*). Nevertheless, when asked to detail all of the allegations that support their reverse payment allegations at oral argument, the MSP Plaintiffs did not cite these allegations. (Tr. of Aug. 18, 2023 Oral Arg. at 223:22–224:2). Further, in their Moving Brief, the Celgene Defendants indicated that it was their understanding that all of the Insurer Plaintiffs and MSP Plaintiffs had expressly disclaimed having any well-founded allegations with respect to the legality of any Celgene patent settlement other than the Celgene-Natco agreement. (Mov. Br. at 7–8 n.3). Despite this clear assertion by the Celgene Defendants, the MSP Plaintiffs set forth no argument in their Opposition Brief to contest this understanding. Nor did they set forth any argument to explain how they had adequately alleged a reverse payment with respect to Celgene's settlement agreements with Alvogen, Hetero, Apotex, and Sun. (*See generally* Opp. Br.). As such, the Court finds any such argument by the MSP Plaintiffs waived. *Market*, 828 F. Supp. 2d at 773. Regardless, the MSP Plaintiffs' conclusory allegation that

Celgene's settlement agreements with Alvogen, Hetero, and Apotex likely amounted to "pay-for-delay" agreements (MSP SAC ¶¶ 436, 460 & 468) are plainly insufficient to plead a reverse payment under *Actavis*. Further, to the extent that the MSP Plaintiffs challenge the volume limited nature of the agreement entered into by Celgene and Alvogen and Celgene and Sun, the Court relies on the same reasoning it employed in Section III(C)(iii)(a) (*supra* at 143–162) and finds that the MSP Plaintiffs have failed to plausibly allege that the volume-limited nature of those agreements amounts to a reverse payment. Further, the MSP Plaintiffs assert that the agreements into which Celgene entered with Alvogen and Sun amounted to reverse payments because under those agreements, "Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched." (MSP SAC ¶¶ 432 & 443). Such speculative and conclusory allegations are plainly insufficient to plead a reverse payment under *Actavis*. Accordingly, insofar as the MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by entering into a reverse payment settlement agreement with Alvogen, Sun, Hetero, and/or Apotex, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

iv. The *Walker Process* Fraud Allegations

The Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act in part by procuring some patents covering Revlimid through fraud on the USPTO and then enforcing those fraudulently obtained patents against competitors in litigation. (Opp. Br. at 27–33). More specifically, the Insurer Plaintiffs allege that Celgene fraudulently obtained the following patents: (i) the '517 Patent; (ii) the '740 Method of Treatment Patent; and (iii) certain REMS Patents. (Humana Am. Compl. ¶¶ 252–276 & 301–321). The MSP Plaintiffs allege that Celgene fraudulently obtained the following patents (i) the '517 Patent; (ii)

the '800 Patent and '217 Polymorph Patents; and (iii) certain REMS Patents. (MSP SAC ¶¶ 264–342).[73] The Insurer Plaintiffs and MSP Plaintiffs then allege that Celgene asserted those fraudulently obtained patents against its competitors through sham litigation to stymy competition. (Humana Am. Compl. ¶¶ 337–44; MSP SAC ¶¶ 343–45). In moving to dismiss the *Walker Process* fraud allegations, the Celgene Defendants contend that Celgene's conduct in asserting its patents is immune from antitrust liability under the *Noerr-Pennington* Doctrine. (*See* Mov. Br. at 12–27; Reply at 5–14). In opposition, the Insurer Plaintiffs and MSP Plaintiffs contend that Celgene is not entitled to immunity under *Noerr-Pennington* because it obtained some of its patents that were later asserted in litigation through fraud. (Opp. Br. at 26–33). The Court will analyze whether this component of the overall scheme can on its own support a claim under Section 2 of the Sherman Act based on a theory of *Walker Process* fraud. For the reasons set forth below, the Court finds that it cannot.

"Rooted in the First Amendment and fears about the threat of liability chilling political speech," *Noerr-Pennington* immunity provides "immun[ity] from antitrust liability" to parties "who petition[ ] the government for redress." *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001). Filing a lawsuit essentially petitions the government for redress and is therefore generally protected from antitrust liability by *Noerr-Pennington* immunity. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999). The Supreme Court has carved out two exceptions to *Noerr-Pennington* immunity. *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 9589217, at *10 (D.N.J. Oct. 29, 2015). The first exception, "which

[73] While the MSP Plaintiffs initially asserted that their allegations of *Walker Process* fraud were aligned with the allegations made by the Insurer Plaintiffs made, including those with respect to Celgene's Method of Treatment Patents (Tr. of Sept. 8, 2023 Oral Arg. at 13:18–25), the MSP Plaintiffs later clarified that they are not asserting *Walker Process* fraud with respect to the '740 Method of Treatment Patent, which is the only method of treatment patent that the Insurer Plaintiffs claim was obtained by fraud. (*Id.* at 71:16–20; Opp. Br. at 27–33).

relates solely to patents" and is relevant here, is based on *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). *Id.* (citing *Walker Process*, 382 U.S. 172 (1965)). The second exception, which will be addressed below in connection with the sham litigation allegations, arises if a lawsuit is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

In *Walker Process*, the Supreme Court held that "the maintenance and enforcement of a patent obtained by fraud on the [USPTO]" may form the basis of an action under Section 2 of the Sherman Act. *See Walker Process*, 382 U.S. at 173–74. To plead a claim for relief under Section 2 of the Sherman Act on a *Walker Process* theory, a plaintiff must allege two conditions. "First, the plaintiff must show that the defendant procured the relevant patent by knowing and willful fraud on the [USPTO] or (in the case of an assignee) that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012). As to this first condition, the Supreme Court "made clear that the invalidity of the patent [i]s not sufficient; a showing of intentional fraud in its procurement [i]s required." *Id.* (citing *Walker Process*, 382 U.S. at 176–77). Notably, it is the *enforcement* of a patent procured by fraud that may give rise to a Sherman Act claim; mere procurement without more does not "affect the welfare of the consumer and cannot in itself violate the antitrust laws." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1418 n.16 (Fed. Cir. 1987); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1357–58 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006); *Vendo Co. v. Lektro-Vend Corp.*, 433 U.S. 623, 644 n. *10 (1977) (Blackmun, J., concurring) ("[The Supreme Court] held only that the enforcement of a patent procured by fraud on the Patent Office could state a claim under § 2

of the Sherman Act . . . ."); *Walker Process*, 382 U.S. at 174. "Second, the plaintiff must prove all the elements otherwise necessary to establish a Sherman Act monopolization charge." *Ritz Camera & Image, LLC*, 700 F.3d at 506 (citations omitted). As to this second condition, "the Court incorporated the rules of antitrust law generally." *Id.* (citing *Walker Process*, 382 U.S. at 180 (Harlan, J., concurring)). "[W]hether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws" is resolved by applying Federal Circuit law, while Third Circuit law applies "to issues involving other elements of antitrust law." *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998).

Under the first condition, a plaintiff alleging that a patent was procured through fraud under *Walker Process* must show:

> (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted.

C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). The standard of materiality "in a *Walker Process* case requires that the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (citation omitted). Further, while *Walker Process* intent may be inferred from the facts and circumstances of a case, "[a] mere failure to cite a reference to the [USPTO] will not suffice" to show an intent to defraud because "the applicant could have had a good-faith belief that disclosure was not necessary, or simply have forgotten to make the required disclosure." *Id.* (citation and internal quotation marks omitted). "[T]here must be evidence of intent separable from the simple fact of the omission." *Id.* However, "[a] false or clearly misleading prosecution statement may permit an inference that the statement was made

with deceptive intent." *Id.* "For instance, evidence may establish that a patent applicant knew one fact and presented another, thus allowing the factfinder to conclude that the applicant intended by the misrepresentation to deceive the examiner." *Id.* In addition, "[l]ike all fraud-based claims, *Walker Process* allegations are subject to the pleading requirements of Fed. R. Civ. P. 9(b)." *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev'd on other grounds*, 549 U.S. 118 (2007). And to satisfy Rule 9(b), a plaintiff must plead the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal–Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

a. The '517 Compound Patent

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene intentionally misrepresented and omitted material facts before the USPTO to obtain the '517 Compound Patent, which covers the composition of matter for Revlimid. (Opp. Br. at 28–31). As recounted above, after the '517 Patent was issued, Celgene filed a request for reexamination concerning the '517 Patent in view of the (i) D'Amato Patents and (ii) Leibovich references. (Humana Am. Compl. ¶ 261). On February 22, 1999, the USPTO rejected all of the claims of the '517 Patent as obvious over the D'Amato Patents in view of the Leibovich References. (*Id.* ¶ 264). On February 25, 1999, Celgene submitted a request for reconsideration and attached a declaration from Celgene's then Chief Scientific Officer, Dr. Stirling, as support for its request. (*Id.* ¶ 265). In the declaration, Dr. Stirling explained that tests were conducted on various compounds to evaluate their relative activities, including on two compounds he identified diagrammatically—Compound 1 and Compound 2. (*Id.* ¶ 266). The Stirling Declaration explained that Compound 2 was found to be over 10,000 fold more active than Compound 1. (*Id.*

¶ 267). In its request for reconsideration, counsel for Celgene, Mr. Collins, maintained that even if the D'Amato Patents and Leibovich References were deemed sufficient to establish obviousness, any finding of obviousness was rebutted by Dr. Stirling's Declaration, which demonstrated an unexpected property of Compound 2, corresponding to the "amino compound of the present claims" of the '517 Patent. (*Id.* ¶ 268). Shortly thereafter, the USPTO issued a notice of intent to issue a reexamination certificate allowing the clams of the '517 Patent. (*Id.* ¶ 269).

The Insurer Plaintiffs allege that the unexpected results of Compound 2 did not pertain to any of the compounds claimed by Claim 10 of the '517 Patent. (*Id.* ¶ 270). More specifically, they allege that Compound 2 corresponded to a compound known as pomalidomide, which is only mentioned in Claim 8 of the '517 Patent as part of a method of treatment claim, but is not covered by Claim 10, which claims four compounds, including lenalidomide. (*Id.* ¶¶ 270–72). As such, because counsel for Celgene stated that Compound 2 corresponded to the "amino compound of the present claims" of the '517 Patent (*id.* ¶ 268), the Insurer Plaintiffs allege that the Stirling Declaration misled the examiner into believing that *all of the claims* of the '517 Compound Patent were patentable, when in fact the patentability of Claim 10 could not be supported by the unexpected properties of Compound 2. (*Id.* ¶ 274). Further, the Insurer Plaintiffs allege that even though Dr. Stirling states in his declaration that he performed testing on "various compounds" he concealed the rest of the data and cherrypicked the results that would best support his claim of unexpected results. (*Id.*). Further, they allege that these allegations support a finding of fraudulent conduct by Dr. Stirling and "potentially" by Celgene's in-house and outside counsel who submitted the request for reconsideration and characterized Compound 2 as corresponding to the "amino compound of the present claims" of the '517 Patent. (*Id.* ¶¶ 268 & 276). In other words,

they allege that the Stirling Declaration and the representations made in the filing that accompanied the Stirling Declaration were false and misleading. (Tr. of Sept. 8, 2023 Oral Arg. at 38:3–6).[74]

The Celgene Defendants argue that the Insurer Plaintiffs have failed to plead that the '517 Compound Patent was procured by fraud with the requisite particularity necessary under Rule 9(b). (Mov. Br. at 18). To start, though the Insurer Plaintiffs allege that the Stirling Declaration, which presented data regarding Compound 2, did not support the patentability of all of the claims of the '517 Compound Patent, the Celgene Defendants argue that the examiner reviewed the data regarding Compound 2 and found that it supported issuing the patent. (*Id.*). As such, they contend that the Insurer Plaintiffs' allegations of fraud amount only to a disagreement with the USPTO. (*Id.*). Further, the Celgene Defendants argue that the Insurer Plaintiffs have not pled, as required, a misrepresentation sufficiently material that the examiner would not have issued the '517 Compound Patent but for the misrepresentation. (*Id.* at 18–19). They explain that the Insurer Plaintiffs cannot meet the materiality requirement because the Patent Trial and Appeal Board ("PTAB") later upheld the '517 Patent during an *inter partes* review ("IPR") without relying on the submitted data regarding Compound 2 in the Stirling Declaration in any respect. (*Id.* at 19).

By way of background, in 2015, the Coalition for Affordable Drugs ("CFAD") filed a petition requesting IPR of Claims 1–10 of the '517 Compound Patent. *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01169, 2015 WL 7304675, at *1 (P.T.A.B. Nov. 16, 2015). In the petition, CFAD argued that the claims of the '517 Compound Patent, including Claim 10, were invalid in light of a number of prior art references. *See generally id.* After

[74] In their Opposition Brief, the Insurer Plaintiffs assert that when Celgene first procured the '517 Compound Patent, it intentionally omitted prior art that rendered the patent obvious, including the D'Amato Patents and Leibovich References which were later used to reject the claims of the '517 Compound Patent during reexamination. (Opp. Br. at 28). Nevertheless, at oral argument the Insurer Plaintiffs clarified that they are not asserting a Section 2 claim based on a theory of *Walker Process* fraud against the Celgene Defendants for intentionally failing to submit the D'Amato Patents and Leibovich References to the USPTO during the *initial* examination of the '517 Compound Patent. (Tr. of Sept. 8, 2023 Oral Arg. at 23:8–19).

considering the petition, the PTAB declined to institute IPR because CFAD had not established a reasonable likelihood that it would prevail in showing the unpatentability of any claim challenged in the petition. *Id.* at *1.[75] As such, the Celgene Defendants assert that the data in the Stirling Declaration cannot have been material to patentability because the PTAB deemed each claim patentable without reinforcement from that data. (Mov. Br. at 19). The Insurer Plaintiffs argue that they have sufficiently alleged that Celgene intentionally misrepresented and omitted material facts before the USPTO to re-obtain its Revlimid '517 Compound Patent. (Opp. Br. at 28). Though the Celgene Defendants argue that the data in the Stirling Declaration must have supported issuing the patent because the examiner reviewed the submitted data, the Insurer Plaintiffs contend that such an argument ignores the fact that Celgene caused the examiner to believe the data it was reviewing related to a compound claimed by Claim 10 of the '517 Patent, when in fact the examiner was reviewing data for a different compound. (*Id.* at 29–30). In addition, the Insurer Plaintiffs argue that the PTAB's 2015 decision not to institute review of the '517 Compound Patent's validity does not immunize Celgene's fraud because the IPR procedure permits challengers to raise only a narrow subset of invalidity arguments, not including fraud, and does not affirm a patent's validity. (*Id.* at 30–31). For the reasons set forth below, the Court finds that the Insurer Plaintiffs have failed to allege that Celgene violated Section 2 of the Sherman Act under a *Walker Process* fraud theory by intentionally misrepresenting and omitting material facts before the USPTO to obtain the '517 Compound Patent.

To start, with respect to the Stirling Declaration, the Insurer Plaintiffs have failed to plead that the Stirling Declaration contained a false representation of a fact material to patentability. The

[75] Other courts have taken judicial notice of PTAB decisions declining to institute IPR on a motion to dismiss. *See, e.g.*, *Humira*, 465 F. Supp. 3d at 823 n.5; *see also Princeton Digital Image Corp. v. Konami Digital Ent. Inc.*, No. 12-1461, 2017 WL 239326, at *3 n.7 (D. Del. Jan. 19, 2017). As such, the Court properly considers such decisions for purposes of the present motion.

Insurer Plaintiffs allege that the Stirling Declaration misled the examiner into believing that *all of the claims* of the '517 Compound Patent were patentable, when in fact the patentability of Claim 10 could not be supported by the unexpected properties of Compound 2. (Humana Am. Compl. ¶¶ 272 & 274). However, there is nothing within the Stirling Declaration itself to support such an inference. More specifically, though the Insurer Plaintiffs allege that Celgene's counsel, who submitted the request for reconsideration, characterized Compound 2 as the "amino compound of the present claims" of the '517 Patent, thereby misleading the examiner into thinking that Compound 2 supported the patentability of *all of the claims* of the '517 Patent, they do not allege that the Stirling Declaration ever made such a representation. (*Id.* ¶¶ 265–76). Rather, they merely allege that to support Celgene's request for reconsideration, Dr. Stirling submitted a declaration, which explained that tests were conducted on various compounds to evaluate their relative activities, including on Compound 1 and Compound 2, and explained that Compound 2 was found to be over 10,000 fold more active than Compound 1. (*Id.* ¶¶ 265–67). The Insurer Plaintiffs do not allege that Dr. Stirling fraudulently misrepresented Compound 2 as corresponding to any of the compounds covered by Claim 10 of the '517 Patent. Nor do they allege that Dr. Stirling indicated in his Declaration that the testing he submitted supported the patentability of *all of the claims* of the '517 Compound Patent. As such, the Insurer Plaintiffs have failed to plead that the Stirling Declaration contained a false representation of a fact material to patentability. Further, the Insurer Plaintiffs have failed to plead sufficient facts from which it is reasonable to infer that Dr. Stirling acted with the specific intent to deceive the patent examiner into thinking that Compound 2 supported the patentability of *all of the claims* of the '517 Patent. As the Celgene Defendants pointed out at oral argument, though Dr. Stirling may not have identified Compounds 1 and 2 by name in his Declaration, the Insurer Plaintiffs allege that he clearly represented which

Compounds he was referring to by illustrating them diagrammatically. (Tr. of Sept. 8, 2023 Oral Arg. at 30:19–21; Humana Am. Compl. ¶ 266). The Court cannot draw the inference that Dr. Stirling intended to deceive the examiner into thinking that the testing results of Compound 2 supported the patentability of *all of the claims* of the '517 Patent, including Claim 10, which did not cover Compound 2, when Dr. Stirling provided the examiner with a diagram that specifically illustrated the Compounds he used for testing.[76]

To be sure, though the Insurer Plaintiffs have failed to plead that the Stirling Declaration contained a false representation of a fact material to patentability they do plead that Dr. Stirling made a deliberate *omission* of fact. More specifically, they allege that even though Dr. Stirling stated that he performed testing on "various compounds," he concealed the rest of the testing data and cherrypicked the results that would best support his claim of unexpected results. (*Id.* ¶ 273). As an initial matter, as the Celgene Defendants pointed out at oral argument, the Insurer Plaintiffs have failed to plead that this omission of testing results was but-for material to patentability—that the '517 Patent would not have been granted if Celgene had disclosed additional testing data. (Tr. of Sept. 8, 2023 Oral Arg. at 57:3–8; Humana Am. Compl. ¶¶ 265–76). Further, the Insurer Plaintiffs have failed to plead sufficient facts from which it is reasonable to infer that Dr. Stirling acted with the specific intent to deceive the patent examiner when choosing which data to include in his Declaration. As described above, while *Walker Process* intent may be inferred from the facts and circumstances of a case, "there must be evidence of intent separable from the simple fact of [an] omission." *Dippin' Dots, Inc.*, 476 F.3d at 1347; *see also C.R. Bard*, 157 F.3d at 1365

[76] At oral argument, the Insurer Plaintiffs suggested that Dr. Stirling's intent to deceive could be inferred from the fact that he was working with Celgene's counsel, Mr. Collins, who characterized Compound 2 as the "amino compound of the present claims" of the '517 Patent (Humana Am. Compl. ¶ 268), thereby misleading the examiner into thinking that Compound 2 supported the patentability of *all of the claims* of the '517 Patent. (Tr. of Sept. 8, 2023 Oral Arg. at 64:4–19). However, as the Celgene Defendants pointed out (*id.* at 64:20–24), the Insurer Plaintiffs at no point allege in their Amended Complaint that Dr. Stirling worked with Mr. Collins to mischaracterize Compound 2. (Humana Am. Compl. ¶¶ 264–76). As such, this argument is unavailing.

("Deceptive intent is not inferred simply because information was in existence that was not presented to the examiner; and indeed, it is notable that in the usual course of patent prosecution many choices are made, recognizing the complexity of inventions, the virtually unlimited sources of information, and the burdens of patent examination.") (citation omitted). Here, the Insurer Plaintiffs have failed to plausibly allege evidence of Dr. Stirling's intent to deceive the examiner separable from the simple fact that the Stirling Declaration may have failed to include additional data on other tested compounds. For example, the Insurer Plaintiffs do not provide any allegations indicating that Dr. Stirling knew that testing results on other compounds—which he allegedly failed to present in his Declaration—would not have supported the patentability of all the claims of the '517 Patent, such that the Court could draw the inference that he intended for the Declaration to deceive the examiner by omitting such results. *Dippin' Dots*, 476 F.3d at 1347. As such, the Insurer Plaintiffs have failed to plead sufficient facts from which it is reasonable to infer that Dr. Stirling acted with the specific intent to deceive the patent examiner when submitting his Declaration. *Dippin' Dots, Inc.*, 476 F.3d at 1347; *see also Jersey Asparagus Farms, Inc. v. Rutgers Univ.*, 803 F. Supp. 2d 295, 310–12 (D.N.J. 2011) (finding that complaint failed to plead specific intent to deceive to support *Walker Process* fraud where there was no allegation that the defendant intentionally omitted the reference to prior uses/sales to defraud the PTO); *Westlake Servs., LLC v. Credit Acceptance Corp.*, No. 15-7490, 2015 WL 9948723, at *7 (C.D. Cal. Dec. 7, 2015) (finding that complaint failed to plead specific intent to deceive to support *Walker Process* fraud claim where it alleged nothing more than that defendant withheld references from the PTO).

Next, though the Insurer Plaintiffs allege that Mr. Collins made a false representation of fact in Celgene's accompanying request for reconsideration, they have failed to plead sufficient facts from which it is reasonable to infer that Celgene's counsel, Mr. Collins, acted with the

specific intent to deceive the patent examiner by submitting his request for reconsideration and supporting Stirling Declaration. As recounted above, the Insurer Plaintiffs allege that Mr. Collins made a false representation of fact and misled the examiner into believing that *all of the claims* of the '517 Compound Patent were patentable by characterizing Compound 2 as the "amino compound of the present claims" of the '517 Patent in Celgene's request for reconsideration. (Humana Am. Compl. ¶¶ 268 & 276; Opp. Br. at 29). This statement, however, is insufficient for the Court to infer that Mr. Collins acted with the intent to deceive the examiner. To start, the Insurer Plaintiffs at no point allege that Mr. Collins acted with the specific intent to deceive the examiner; they only allege that Dr. Stirling acted with such intent. (Humana Am. Compl. ¶¶ 275–76). In fact, they specifically allege that Celgene's conduct during the reexamination of the '517 Compound Patent only "*potentially*" supports a finding of fraud on the part of Mr. Collins who submitted the request for reconsideration and supporting Stirling Declaration. (*Id.* ¶ 276 (emphasis added)). The Court cannot infer that Mr. Collins acted with the specific intent to deceive the examiner based on such speculative allegations. *Dippin' Dots, Inc.*, 476 F.3d at 1347; *see also Smith v. LifeVantage Corp.*, 429 F. Supp. 3d 1275, 1288 (D. Utah 2019) (finding that the plaintiffs failed to plead the requisite intent to support a *Walker Process* fraud claim where they only offered speculation as to the defendants' motivation). In addition, even though Mr. Collins may have characterized Compound 2 as the "amino compound of the present claims" of the '517 Patent (Humana Am. Compl. ¶¶ 268 & 276), he also, as the Insurer Plaintiffs allege, specifically submitted Dr. Stirling's Declaration to support Celgene's request for reconsideration. (*Id.* ¶ 261). As the Celgene Defendants pointed out at oral argument, though Dr. Stirling may not have identified Compounds 1 and 2 by name in his Declaration, he clearly represented which Compounds he was referring to by illustrating them diagrammatically. (Tr. of Sept. 8, 2023 Oral

Arg. at 30:19–21; Humana Am. Compl. ¶ 266). As such, the Court cannot plausibly infer that Mr. Collins specifically intended to deceive the examiner into believing that Dr. Stirling's testing results supported the patentability of *all of the claims* of the '517 Patent, including those claims that did not cover Compound 2, when he submitted a Declaration in support of his request that clearly laid out what Compound 2 corresponded to diagrammatically. Further undercutting any inference that either Mr. Collins or Dr. Stirling acted with the specific intent to deceive the examiner is the fact that Celgene itself initiated the request for reexamination. More specifically, as discussed already, after the '517 Patent was issued, Celgene filed a request for reexamination concerning the '517 Patent with the USPTO because of a question raised by a non-adversarial third party as to the significance of certain prior art. (Humana Am. Compl. ¶ 261). The fact that Celgene voluntarily brought prior art to the examiner's attention during reexamination supports the inference that those involved in the reexamination, including Mr. Collins and Dr. Stirling, were acting in good faith, rather than with the specific intent to deceive the examiner. *See, e.g.*, *Pac. Biosciences of California, Inc. v. Oxford Nanopore Techs., Inc.*, No. 17-1353, 2019 WL 668843, at *3 (D. Del. Feb. 19, 2019) (finding that defendant failed to adequately allege specific intent to support counterclaim of inequitable conduct and *Walker Process* fraud where there were objective indications of candor and good faith). As such, the Insurer Plaintiffs have failed to plead sufficient facts from which it is reasonable to infer that Mr. Collins or Dr. Stirling acted with the specific intent to deceive the patent examiner when submitting Celgene's request for reconsideration. In sum, the Court finds that the Insurer Plaintiffs have failed to allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene

allegedly intentionally misrepresented and omitted material facts before the USPTO to obtain the '517 Compound Patent.[77]

The MSP Plaintiffs' Allegations. The Court likewise finds that the MSP Plaintiffs have failed to allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene intentionally misrepresented and omitted material facts before the USPTO to obtain the '517 Compound Patent. Here, the MSP Plaintiffs generally allege that the '517 Patent was procured by fraud because the USPTO was not aware of key prior art when the '517 Patent was granted. (MSP SAC ¶¶ 264–65). The MSP Plaintiffs' Second Amended Complaint does not contain any allegations regarding the fraud Celgene allegedly committed during the reexamination of the '517 Patent through the Stirling Declaration.

As an initial matter, though the MSP Plaintiffs generally allege that the USPTO was not aware of key prior art when the '517 Patent was granted, they fail to plead who made the material omission, when such an omission took place, and which prior art references were not disclosed to the examiner. Such conclusory allegations clearly do not allege fraud, let alone with the specificity required under Rule 9(b). *See Exergen*, 575 F.3d at 1328 (to satisfy Rule 9(b) plaintiff must plead the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO."). Nor do the MSP Plaintiffs set forth any allegations regarding how Celgene acted with the specific intent to defraud the USPTO in failing to submit those references, or why those references were but-for material to patentability. (MSP SAC ¶¶ 264–65). Such allegations are plainly insufficient to meet the pleading requirements for *Walker Process* fraud. *See e.g., In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 583 (E.D. Pa. 2018) (finding that the plaintiffs

[77] Because the Insurer Plaintiffs have failed to plausibly allege that either Dr. Stirling or Mr. Collins acted with the specific intent to deceive the examiner during the reexamination of the '517 Compound Patent, the Court need not address whether they have adequately alleged the other elements that would plausibly demonstrate that they procured the '517 Patent through fraud under a *Walker Process* fraud theory. *See C.R. Bard, Inc.*, 157 F.3d at 1364.

failed to plead *Walker Process* fraud where they failed to specify the substance of the alleged misleading statements before the USPTO, or how the defendants breached their duty of candor). As such, the Court finds that the MSP Plaintiffs have failed to allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene allegedly omitted material facts before the USPTO to obtain the '517 Compound Patent.

b. The '740 Method of Treatment Patent

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene allegedly intentionally misrepresented and omitted material facts before the USPTO to obtain the '740 Method of Treatment Patent. (Opp. Br. at 32). During the prosecution of the '740 Patent, the USPTO rejected the claims as anticipated and/or obvious over a number of prior art references. (Humana Am. Compl. ¶ 315). To overcome these rejections, Celgene's then Vice President and Chief Medical Officer Jerome Zeldis, the inventor of the '740 Patent, submitted a declaration (the "First Zeldis Declaration") in which Zeldis asserted that he conceived of the presently claimed invention prior to March 8, 2002—earlier than any of the prior art references the examiner relied on in rejecting the claims of the '740 Patent. (*Id.* ¶ 316). To support this assertion, Zeldis submitted a clinical trial protocol and abstract, which described the studies Zeldis conducted with respect to the invention. (*Id.* ¶¶ 316–17). However, the Insurer Plaintiffs allege that neither the clinical trial protocol nor the abstract contained any date information. (*Id.* ¶¶ 318–19). Thereafter, the USPTO again rejected the claims of the '740 Patent as obvious over newly cited prior art references. (*Id.* ¶ 320). In response, Celgene submitted a second declaration from Zeldis (the "Second Zeldis Declaration") in which Zeldis claimed that he conceived of the presently claimed invention prior to July 19, 2001—earlier than any of the newly cited prior art

references the examiner relied on in rejecting the claims of the '740 Patent for a second time. (*Id.*). To support this assertion, Zeldis again referenced the clinical trial protocol and the abstract as support. (*Id.*). After the Second Zeldis Declaration was submitted, the '740 Patent was granted. (*Id.*). The Insurer Plaintiffs allege that Celgene obtained the '740 Patent by fraud because the clinical trial protocol and abstract did not contain any information concerning when Zeldis conceived of his claimed invention, and so did not support a finding that Zeldis conceived of the claimed invention earlier than the prior art references cited by the examiner. (*Id.* ¶¶ 318–21).[78]

With respect to the Insurer Plaintiffs' allegations regarding the fraudulent procurement of the '740 Method of Treatment Patent, the Celgene Defendants argue that the Insurer Plaintiffs cannot establish fraud because their allegations fly in the face of black-letter USPTO procedures. (Reply at 10). The Insurer Plaintiffs allege that Celgene procured the '740 Method of Treatment Patent by fraud because the inventor of the patent relied on documents, without any relevant date information, to assert that he conceived of the present invention before the prior art references relied on by the examiner in rejecting the patent. (Humana Am. Compl. ¶¶ 315–21). The Celgene Defendants, however, point out that the Manual of Patent Examining Procedure ("MPEP")[79] expressly permits applicants to support an earlier date of invention through an oath or declaration if the dates of supporting exhibits have been removed or blocked off. (Reply at 11). As such, the

[78] The MSP Plaintiffs' Second Amended Complaint does not contain allegations regarding Celgene's fraud in obtaining the '740 Method of Treatment Patent. (*See generally* MSP SAC). While the MSP Plaintiffs initially asserted that their allegations of *Walker Process* fraud were aligned with the allegations made by the Insurer Plaintiffs, including with respect to Celgene's Method of Treatment Patents (Tr. of Sept. 8, 2023 Oral Arg. at 13:18–25), the MSP Plaintiffs later clarified that they are not asserting *Walker Process* fraud with respect to the '740 Method of Treatment Patent, which is the only method of treatment patent that the Insurer Plaintiffs claim was obtained by fraud. (*Id.* at 71:16–20).

[79] "The MPEP [is] commonly relied upon as a guide to patent attorneys and patent examiners on procedural matters." *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys*, 90 F. Supp. 2d 522, 536 n.7 (D.N.J. 2000) (citation omitted). "While the MPEP does not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Id.*

Celgene Defendants assert that they could not have defrauded the USPTO by following its own procedures. (*Id.*). For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that the Insurer Plaintiffs have failed to allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene allegedly intentionally misrepresented and omitted material facts before the USPTO to obtain the '740 Method of Treatment Patent.

To start, the Insurer Plaintiffs do not sufficiently allege a false representation or omission of a material fact with respect to Celgene's conduct in prosecuting the '740 Patent. When the '740 Patent was first rejected during prosecution over the prior art, Zeldis submitted a declaration asserting that he conceived of the presently claimed invention prior to March 8, 2002, or earlier than any of the prior art references the examiner relied on in rejecting the claims of the '740 Patent, and relied on the undated clinical trial protocol and the abstract as support. (Humana Am. Compl. ¶¶ 316–17). Thereafter, the USPTO again rejected the claims of the '740 Patent as obvious over other prior art references. (*Id.* ¶ 320). In response, Celgene submitted a second declaration from Zeldis, in which Zeldis claimed that he conceived of the presently claimed invention prior to July 19, 2001, or earlier than any of the new prior art references cited by the examiner and relied on the same undated documents as support. (*Id.*). The Insurer Plaintiffs ask the court to infer that these statements were false based on the fact that the two documents the inventor submitted to support his alleged conception date did not contain any relevant date information. (Opp. Br. at 33). However, as the Celgene Defendants point out, the Insurer Plaintiffs at no point allege that Zeldis's Declarations themselves contained false statements regarding the date of the invention. (Reply at 11). Rather, they merely allege that the dates provided by Zeldis in his Declarations were not supported by the documents he relied on in asserting his alleged conception date—the clinical

protocol and the abstract. (Humana Am. Compl. ¶¶ 316–21; Mov. Br. at 20). The fact that Zeldis may not have provided sufficient support for his claimed conception date does not plausibly indicate that his Declarations were false. Further, Zeldis's second declaration is not inconsistent with his first declaration. At first, Zeldis asserted that he conceived of the invention prior to March 8, 2002, because that was the earliest date that any of the prior art references relied on by the examiner in rejecting the claims of the '740 Patent had been disclosed. (Humana Am. Compl. ¶ 317). Later, when the examiner cited references that had been disclosed earlier, Zeldis asserted that he conceived of the invention prior to July 19, 2001 (*id.* ¶ 320)—a date that is still consistent with his initial statement of "prior to March 8, 2002." (*Id.* ¶ 316). As such, the Insurer Plaintiffs have failed to sufficiently allege that Zeldis's Declarations contained false representations or omissions of material fact.

Nor do the Insurer Plaintiffs allege sufficient facts from which it is reasonable to infer that Zeldis submitted his Declarations with the specific intent to deceive the examiner. While a "false or clearly misleading prosecution statement may permit an inference that the statement was made with deceptive intent" here, the Insurer Plaintiffs do not provide any allegations indicating that Zeldis "knew one fact and presented another" such that the Court could draw the inference that he intended for the Declarations to deceive the examiner. *Dippin' Dots*, 476 F.3d at 1347. More specifically, the Insurer Plaintiffs at no point allege that Zeldis knew his claimed invention dates were false but nevertheless presented those facts to the USPTO to deceive the examiner. *Id.* They only allege that Zeldis did not provide sufficient support for his claimed invention dates. Without any other allegations indicating that Zeldis knew he did not conceive of the invention on the dates asserted in his Declarations, the Court cannot draw the inference that Zeldis was attempting to mislead the examiner. Accordingly, the Insurer Plaintiffs have failed to plead the requisite intent

necessary to support their theory of *Walker Process* fraud as to the '740 Patent. *See Jersey Asparagus Farms, Inc.*, 803 F. Supp. at 310; *Smith*, 429 F. Supp. 3d at 1288.

Further, as the Celgene Defendants point out, the Court cannot plausibly infer that Zeldis submitted his Declarations with the specific intent to deceive the patent examiner because his conduct comported with USPTO procedures. (Reply at 10–11). More specifically, the version of the MPEP that was in effect at the time Zeldis submitted his Declarations expressly permitted applicants to support an earlier date of invention through an oath or declaration if the dates of supporting exhibits had been removed or blocked off. MPEP Section 715.07 (addressing "Establishment of Dates" for purposes of swearing behind a reference: "If the dates of the exhibits have been removed or blocked off, the matter of dates can be taken care of in the body of the oath or declaration" and "if the applicant or patent owner does not desire to disclose his or her actual dates, he or she may merely allege that the acts referred to occurred prior to a specified date.") (Rev. Aug. 2005)). That is precisely what is alleged to have happened here: Zeldis supported his claims of an earlier date of invention through two Declarations because the supporting exhibits did not disclose any relevant date information. (Humana Am. Compl. ¶¶ 316–21). As such, it is implausible that Zeldis was acting with the intent to defraud the USPTO when he appears to have been following its own procedures. *See, e.g.*, *ESCO Corp. v. Cashman Equip. Co.*, 158 F. Supp. 3d 1051, 1063 (D. Nev. 2016) (finding that party did not engage in inequitable conduct by failing to disclose a reference to the examiner when the MPEP provided that the applicant was not required to submit the reference).

In sum, the Court finds that the Insurer Plaintiffs have failed to allege that that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because

Celgene allegedly intentionally misrepresented and omitted material facts before the USPTO to obtain the '740 Method of Treatment Patent.

c. The '800 and '217 Polymorph Patents

The MSP Plaintiffs' Allegations. Though not set forth anywhere in their Opposition Brief, the MSP Plaintiffs indicated for the first time at oral argument that they also allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene allegedly intentionally misrepresented material facts before the USPTO to obtain the '800 and '217 Polymorph Patents. (Tr. of Sept. 8, 2023 Oral Arg. at 13:18–25 & 89:23–90:3; *see also* Opp. Br. at 27–33 (describing in detail the patents that Celgene allegedly procured by fraud to support a *Walker Process* fraud theory, but failing to list the '800 and '217 Polymorph Patents)). To support this supposed *Walker Process* fraud theory, the MSP Plaintiffs generally allege that the '800 Patent and '217 Patent are invalid and were obtained "due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent." (MSP SAC ¶ 270). The Celgene Defendants argue that the MSP Plaintiffs' allegations regarding the polymorph patents are insufficient to withstand a motion to dismiss. (Mov. Br. at 21–23). The Court finds that the MSP Plaintiffs have failed to plead that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene intentionally misrepresented material facts before the USPTO to obtain the '800 and '217 Polymorph Patents.

As an initial matter, other than alleging in one sentence that the '800 Patent and '217 Patent were obtained "due to a failure to disclose publicly available prior art and research from decades earlier" (MSP SAC ¶ 270), the MSP Plaintiffs fail to plead who made the material omission, when such an omission took place, which prior art references were not disclosed to the examiner, and how those references rendered the '800 and '217 Polymorph Patents invalid. Such conclusory

allegations clearly do not allege fraud, let alone with the specificity required under Rule 9(b). *See Exergen*, 575 F.3d at 1328 (to satisfy Rule 9(b) plaintiff must plead the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO"). Nor do the MSP Plaintiffs set forth any allegations regarding how Celgene acted with the specific intent to defraud the USPTO in failing to submit those references, or why those references were but-for material to patentability. (MSP SAC ¶ 270). In other words, their allegations are plainly insufficient to meet the pleading requirements for *Walker Process* fraud. *See, e.g.*, *Remicade*, 345 F. Supp. 3d at 583 (finding that plaintiffs failed to plead *Walker Process* fraud where they failed to specify the substance of the alleged misleading statements before the USPTO, or how defendants breached their duty of candor).[80]

d. The REMS Patents

The Insurer Plaintiffs' and MSP Plaintiffs' Allegations. The Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory because Celgene allegedly intentionally misrepresented and omitted material facts before the USPTO to obtain certain REMS Patents. (Opp. Br. at 31–32). The Celgene Defendants contend that any such allegations must be dismissed. (Mov. Br. at 23). More specifically, the Celgene Defendants argue that the Insurer Plaintiffs and MSP Plaintiffs cannot assert an antitrust injury based on Celgene's alleged enforcement of its REMS Patents because,

[80] At oral argument, the MSP Plaintiffs appeared to suggest that their allegations of *Walker Process* fraud with respect to the '800 and '217 Polymorph Patents were aligned with the Insurer Plaintiffs' allegations of *Walker Process* fraud with respect to those patents. (Tr. of Sept. 8, 2023 Oral Arg. at 90:12–17). Nevertheless, the Insurer Plaintiffs did not assert either at oral argument or in their Opposition Brief that they were alleging *Walker Process* fraud with respect to the '800 and '217 Polymorph Patents. (*See generally* Opp. Br.; *See generally* Tr. of Sept. 8, 2023 Oral Arg.). Regardless, the only allegation in the Insurer Plaintiffs' Amended Complaint that relates to any supposed fraud with respect to the '800 and '217 Patents only states that the '800 and '217 Polymorph Patents "were obtained due to a failure to disclose publicly available prior art and research from decades earlier." (Humana Am. Compl. ¶ 300). As described above, with respect to the MSP Plaintiffs' allegations, such allegations are plainly insufficient to meet the pleading requirements for *Walker Process* fraud.

even if Celgene had not enforced its REMS Patents against its generic competitors, those competitors would still have been prevented from lawfully entering the market by virtue of Celgene's other patents. (Reply at 13–14; Tr. of Sept. 8, 2023 Oral Arg. at 78:19–79:12). The Celgene Defendants further point out that according to the Third Circuit's decision in *Wellbutrin*, an antitrust claim fails if it "does not take into account a valid blocking patent that would lawfully bar generic competition." (Reply at 13 (quoting *Wellbutrin*, 868 F.3d at 165)). For the reasons set forth below, the Court agrees with the Celgene Defendants.[81]

To establish monopolization under Section 2 of the Sherman Act, a plaintiff must show "antitrust injury—that is, [an] injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful." *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 233 (3d Cir. 2013) (internal quotation marks and citation omitted); *Unitherm*, 375 F.3d at 1362. In *Wellbutrin*, the Third Circuit found that the plaintiffs had not established antitrust injury. *Wellbutrin*, 868 F.3d at 169–70. The court started off by noting that in order to establish antitrust injury, the plaintiffs had to show that the harm they claimed to have experienced—increased drug prices—was caused by the complained of settlement agreement. *Id.* at 164–65. The plaintiffs in that case attempted to make this showing by stating that in the absence of the challenged settlement agreement, the generic company would have launched its generic drug at lower prices much earlier. *Id.* The Third Circuit found that the plaintiffs' theory could not establish antitrust injury because it did not take into account the fact that there was a patent which would have blocked the generic from legally launching its product, irrespective of the settlement agreement. *Id.* at 165. Specifically, the court reasoned that "if the launch were stopped because

[81] While "the existence of antitrust injury is not typically resolved through motions to dismiss," courts can and do decide these issues at the 12(b)(6) stage. *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 416–19 (3d Cir. 1997) (citing *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995)).

it was illegal, then the [plaintiffs'] injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch." *Id.* As such, the court found that the plaintiffs could not establish antitrust injury. *Id.* at 169–70.

Here, the Insurer Plaintiffs and MSP Plaintiffs allege that the harm they experienced as a result of Celgene's anticompetitive conduct includes increased drug prices. (Humana Am. Compl. ¶¶ 564–69; MSP SAC ¶¶ 495–501). As such, with respect to the Insurer Plaintiffs' and MSP Plaintiffs' allegations of *Walker Process* fraud as it relates to Celgene's REMS Patents, in order to plausibly establish antitrust injury, the Insurer Plaintiffs and MSP Plaintiffs must show that the harm they claim to have experienced—increased drug prices—was caused by Celgene's enforcement of its allegedly fraudulently procured REMS Patents. This they cannot do. Here, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene enforced its allegedly fraudulently obtained REMS Patents only against Natco, Alvogen, and Apotex. (Humana Am. Compl. ¶¶ 347–63, 388–98 & 446–69; MSP SAC ¶¶ 367–81, 428–37 & 462–69). The MSP Plaintiffs also allege that Celgene enforced its allegedly fraudulently obtained REMS Patents against Dr. Reddy's. (MSP SAC ¶¶ 382–98). As an initial matter, the Insurer Plaintiffs allege that, after Celgene's '720 REMS Patent was invalidated by the PTAB, Celgene agreed to stay all proceedings related to its REMS Patents pending the Federal Circuit's review of the PTAB's decision. (Humana Am. Compl. ¶¶ 395 & 454; *see also* MSP SAC ¶ 466). They further allege that after the Federal Circuit affirmed the PTAB decision, Celgene stopped pressing its REMS Patents in litigation against generics. (Humana Am. Compl. ¶ 302). In fact, the Insurer Plaintiffs allege that Celgene stopped pressing its REMS Patents against Alvogen and Apotex. (Humana Am. Compl. ¶¶ 395 & 454; *see also* MSP SAC ¶ 466). This undercuts any inference that Celgene's enforcement of its allegedly

fraudulently procured REMS Patents is responsible for any generic delay and the harm the Insurer Plaintiffs say they experienced—increased drug prices.

Regardless, *Wellbutrin* made clear that an antitrust claim fails if it "does not take into account [a] blocking patent" that would lawfully bar generic entry. *Wellbutrin*, 868 F.3d at 164–65. Here, as the Celgene Defendants point out (Reply at 13), multiple of Celgene's Method of Treatment Patents expire after Celgene's REMS Patents. (Humana Am. Compl. ¶ 109 (alleging that the '621, '569, '498, '095 Patent, and '622 Method of Treatment Patents expire in 2023 and that the '929 Method of Treatment Patent expires in 2028, while the latest expiration date for any REMS Patents is in 2020); MSP SAC ¶ 110 (same)). As such, the Insurer Plaintiffs and MSP Plaintiffs cannot plausibly allege that Celgene's enforcement of its allegedly fraudulently procured REMS Patents are responsible for any generic delay and, as a result, increased drug prices.

The court's decision in *Humira* is instructive on this point. There, the court, sitting in the Northern District of Illinois, found the "plaintiffs' theory of antitrust injury . . . not plausible" on a motion to dismiss because the "complaint call[ed] many of [the defendant's] patents 'weak,' its patent applications 'dubious,' sa[id] that some of the patents were 'obvious in light of prior art,' and identifie[d] four patents that were issued as the result of material misrepresentations and omissions to the USPTO," but never alleged that "*all* of [the defendant's] patents were invalid or not infringed." *Humira*, 465 F. Supp. 3d at 844 (citations omitted) (emphasis added). Relying on the Third Circuit's decision in *Wellbutrin*, the court in *Humira* reasoned, "[i]f a drug is not able to launch because launching would infringe *even a single patent*, then the injury (if it could still be called that)" would be caused not by the settlement agreement the plaintiffs alleged was anticompetitive "but by the patent laws prohibiting the launch." *Id.* (quoting *Wellbutrin*, 868 F.3d at 165). It further explained, "[i]f the reason the biosimilar manufacturers could not make it to

market was that [the defendant] had a patent that prevented them from doing so, it was the patent—and not [the defendant's] other conduct—that was the but-for cause of the monopoly prices." *Id.* As such, the court found that the plaintiffs' theory of antitrust injury was speculative as a matter of law because the defendant had an impassable IP portfolio, and all it would have taken was one valid and infringed patent to preclude other competitors from entering the market. *Id.* at 844–46.

The Court finds the present facts analogous. As recounted above, here, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene enforced its allegedly fraudulently obtained REMS Patents only against Natco, Alvogen, and Apotex. (Humana Am. Compl. ¶¶ 347–63, 388–98 & 446–69; MSP SAC ¶¶ 367–81, 428–37 & 462–69). The MSP Plaintiffs also allege that Celgene enforced its allegedly fraudulently obtained REMS Patents against Dr. Reddy's. (MSP SAC ¶¶ 382–98). While the Insurer Plaintiffs and MSP Plaintiffs allege that many of Celgene's patents were weak, invalid, and/or not infringed by those generic manufacturers, they at no point allege that *all* of Celgene's patents were invalid and/or were not infringed by Natco, Alvogen, Apotex, or Dr. Reddy's including its Method of Treatment Patents that expire after its REMS Patents.[82] (*See, e.g.*, Humana Am. Compl. ¶¶ 347–63 (setting forth no allegations as to how '929 Method of Treatment Patent expiring after REMS Patents was invalid and/or not infringed by Natco[83] and stating no plausible allegations as to how '569, '498, '095, and '622 Method of

[82] While the Insurer Plaintiffs and MSP Plaintiffs allege that all of Celgene's patents are invalid, such a conclusory allegation does not suffice. (Humana Am. Compl. ¶ 543; MSP SAC ¶ 473).

[83] The Insurer Plaintiffs do allege that Natco and Lotus (which was later sued along with Alvogen, collectively "Alvogen") filed section viii carveouts as to a number of Method of Treatment Patents. (Humana Am. Compl. ¶ 324). "Where the Orange Book lists a method of use patent that 'does not claim a use for which [a generic ANDA applicant] is seeking approval,' an applicant may instead submit a statement under 21 U.S.C. § 355(j)(2)(A)(viii) averring that the ANDA excludes all uses claimed in the patent ('Section viii statement')." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012) (citing *Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1360–61 (Fed. Cir. 2003)). Through a Section viii statement, a generic can limit the number of patents at issue in litigation by seeking ANDA approval only on certain FDA approved indications, but not on others. (Humana Am. Compl. ¶ 322); 21 U.S.C. § 355(j)(2)(A)(viii). According to the Insurer Plaintiffs, "[o]ften a generic company includes in its proposed label for its generic drug the original approved indication and omits additional indications that are claimed by patents with later expiration dates." (Humana Am. Compl. ¶ 322). "The FDA and Congress encourage generic companies to

Treatment Patents expiring after REMS Patents were invalid[84] and/or not infringed by Natco); Humana Am. Compl. ¶¶ 446–69 (setting forth no plausible allegations as to how '929, '569, '498, '095, '621, and '622 Method of Treatment Patents expiring after REMS Patents were invalid and/or not infringed by Apotex); *id.* ¶¶ 388–98 (setting forth no plausible and only conclusory allegations as to how '569, '498, '095, and '622 Method of Treatment Patents expiring after REMS Patents were invalid and/or not infringed by Alvogen); MSP SAC ¶¶ 367–87, 429–37 & 462–69 (setting forth no allegations as to how '929 Method of Treatment Patent expiring after REMS Patents was invalid and/or not infringed by Natco, Dr. Reddy's, or Alvogen; setting forth only conclusory allegations that '929 Method of Treatment Patent expiring after REMS Patents was invalid and/or not infringed by Apotex; setting forth no allegations that '569, '498, '095, and '622 Method of Treatment Patents expiring after REMS Patents were invalid and/or not infringed by

use Section viii carve outs in order to bring generic drugs to market as soon as possible." (*Id.*). Nevertheless, while the Insurer Plaintiffs allege that Lotus submitted a section viii carveout as to the '929 Method of Treatment Patent, they do not allege that Lotus carved out the '569, '498, '095, '621, and '622 Method of Treatment Patents. (*Id.*). Likewise, while the Insurer Plaintiffs allege that Natco submitted a section viii carveout as to the '621 Method of Treatment Patent, they do not allege that Natco carved out the '929, '569, '498, '095, and '622 Method of Treatment Patents. (*Id.*).

[84] To be sure, the Insurer Plaintiffs allege that the '569, '498, '095, and '622 Method of Treatment Patents were invalid as obvious based on prior art. (Opp. Br. at 38; Humana Am. Compl. ¶¶ 327–29). More specifically, they allege that these patents are subject to strong invalidity challenges, including obviousness. (Humana Am. Compl. ¶¶ 327–28). The Insurer Plaintiffs allege that during prosecution, to overcome the USPTO's rejections for obviousness, Celgene submitted findings that it argued showed it had determined that there were unexpected results in its claimed methods of treating cancer. (*Id.* ¶ 328). For example, during prosecution of the '569 Patent, Celgene allegedly submitted numerous publications to show that its claimed method of treatment had surprising and unexpected effects in treating multiple myeloma patients in comparison to the prior art. (*Id.*). However, because the publications submitted to show those unexpected results post-dated the claimed invention, the Insurer Plaintiffs assert that they did not support a finding of patentability at the time of the invention. (*Id.* ¶ 329). But, as the Celgene Defendants point out (Mov. Br. at 20) and as will be further described below, the Federal Circuit has made clear "that evidence of unexpected results may be used to rebut a case of *prima facie* obviousness even if that evidence was obtained after the patent's filing or issue date." *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011). At oral argument, the Insurer Plaintiffs conceded that the mere fact that Celgene submitted to the USPTO reports on the unexpectedly good results of the invention of the '569 Patent that post-dated the date of invention does not indicate that the patents claiming methods of treating cancer are invalid as obvious. (Tr. of Sept. 8, 2023 Oral Arg. at 159:16–160:6). Because their Amended Complaint contains no other allegations explaining why the '569 '498, '095, and '622 Method of Treatment Patents were obvious, the Insurer Plaintiffs' Amended Complaint contains no plausible allegations that those patents were invalid. Their conclusory allegations that those patents were otherwise obvious and "that generic manufacturers had strong invalidity challenges to the multiple myeloma method of treatments patents" does not alter this conclusion. (Humana Am. Compl. ¶¶ 327–29).

Natco and Apotex; and setting forth only conclusory allegations that '569, '498, '095, '621, and '622 Method of Treatment Patents expiring after REMS Patents were invalid and/or not infringed by Dr. Reddy's and Alvogen)). Because all it would have taken is one valid and infringed patent to preclude these generics from entering the market, the Insurer Plaintiffs and MSP Plaintiffs cannot plausibly allege that Celgene's enforcement of certain of its fraudulently procured REMS Patents is responsible for any generic delay and the harm they say they experienced—increased drug prices. *Wellbutrin*, 868 F.3d at 165; *see also* Phillip E. Areeda & Herbert Hovenkamp, Fundamentals of Antitrust Law § 3.04[B] (rev. 4th ed. Supp. 2015) ("[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").[85]

In sum, the Court finds that the Insurer Plaintiffs and MSP Plaintiffs have failed to allege that the Celgene Defendants violated Section 2 of the Sherman Act under a *Walker Process* fraud theory as to any of Celgene's patents.[86] Accordingly, insofar as the Insurer Plaintiffs and MSP

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[85] The Insurer Plaintiffs and MSP Plaintiffs also argue that their other allegations indicate that, absent Celgene's anticompetitive conduct, competitively acting companies in the position of Natco and Celgene would have agreed on an earlier date for free market generic competition. (Opp. Br. at 37 n.135). More specifically, as already recounted, they allege that Celgene entered into an anticompetitive agreement with Natco—the first-filer of an ANDA for lenalidomide—to end a then pending patent infringement lawsuit against Natco. (Humana Am. Compl. ¶¶ 347–75 & 418–44; MSP SAC ¶¶ 367–80). The Insurer Plaintiffs and MSP Plaintiffs contend that if not for the anticompetitive settlement agreement, Natco would have been permitted to enter the market earlier. (Opp. Br. at 37 n.135). As such, they contend that they can adequately allege an antitrust injury from Celgene's anticompetitive behavior. However, as already described above, the Insurer Plaintiffs and MSP Plaintiffs have failed to allege that the Celgene-Natco settlement agreement was anticompetitive. *See Humira*, 465 F. Supp. 3d at 846. Regardless, "an injury deriving from the failure to reach a hypothetical procompetitive agreement is 'nothing but speculation.'" *See Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 957 (S.D. Ohio 2010) (quoting *Associated Gen. Contractors*, 459 U.S. at 543). As such, this argument is unavailing. *Humira*, 465 F. Supp. 3d at 846 ("Given that . . . all it would have taken was one valid and infringed patent to preclude market entry until that patent's expiration, it is not plausible that [the allegedly anticompetitive settlement] agreements prevented an even earlier entry date.").

[86] To be sure, courts have stated that when a plaintiff's claim is premised on an overall scheme, it is sufficient for a plaintiff to allege injuries that occurred as a result of the entire scheme, rather than any particular component therein. *Rochester Drug Co-op., Inc. v. Braintree Labs.*, 712 F. Supp. 2d 308, 317 (D. Del. 2010). Nevertheless, as will be described further below, here none of the alleged instances of misconduct are independently anti-competitive and, as such, they are not cumulatively anticompetitive either. *See Eatoni Ergonomics, Inc.*, 486 F. App'x at 191; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (assessing whether plaintiffs had antitrust standing to bring allegations regarding component of the scheme, on its own, before

Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act by procuring its patents through fraud under a *Walker Process* fraud theory, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

v. The Sham Litigation Allegations

The Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants violated Section 2 of the Sherman Act in part by bringing sham patent infringement lawsuits against various generic competitors to enforce patents that were unenforceable, invalid, and/or not infringed. (Opp. Br. at 33–41). More specifically, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene brought sham patent infringement lawsuits against various companies to enforce patents that were unenforceable, invalid, and/or not infringed including its (i) '517 Compound Patent; (ii) Method of Treatment Patents; (iii) polymorph patents; and (iv) REMS Patents. (Humana Am. Compl. ¶¶ 251–539; MSP SAC ¶¶ 260–469). Further, the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene filed sham lawsuits asserting patents that were not listed in the Orange Book. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). In moving to dismiss these allegations, the Celgene Defendants contend that Celgene's conduct in asserting its patents is immune from antitrust liability under the *Noerr-Pennington* doctrine. (Mov. Br. at 16–27; Reply at 5–14). In opposition, the Insurer Plaintiffs and MSP Plaintiffs contend that Celgene engaged in sham litigation, stripping it of any immunity it could otherwise claim under *Noerr-Pennington*. (Opp. Br. at 33–41). The Court will analyze whether this component of the overall scheme, on its own, can support a claim under Section 2 of the Sherman Act based on a theory of sham litigation. For the reasons set forth below, the Court finds that it cannot.

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determining whether allegations regarding scheme as a whole could proceed); *Asacol*, 233 F. Supp. 3d at 266 (same); *Am. Nat'l Mfg. Inc. v. Select Comfort Corp.*, No. 16-0582, 2016 WL 9450472, at *9 (C.D. Cal. Sept. 28, 2016) (same).

As stated above, under the *Noerr-Pennington* doctrine, "[t]hose who petition [the] government for redress are generally immune from antitrust liability." *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc. ("PRE")*, 508 U.S. 49, 56 (1993). That includes the right to sue in federal court. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (holding "the right to petition extends to all departments of the Government," including the courts). As such, a patent owner's initiation of patent infringement litigation receives presumptive immunity from attack under the antitrust laws. *See Rochester Drug Co-op., Inc. v. Braintree Lab'ys*, 712 F. Supp. 2d 308, 316 (D. Del. 2010). The Supreme Court has carved out two exceptions to *Noerr-Pennington* immunity. *Thalomid*, 2015 WL 9589217, at *10. The second exception, relevant to the Insurer Plaintiffs' and MSP Plaintiffs' sham litigation allegations, arises if a lawsuit is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

An allegation of sham litigation consists of two elements. The party invoking the sham litigation exception must show that (i) the lawsuit is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits[;]" and (ii) "the lawsuit conceals an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon[.]" *Miller Indus. Towing Equip. Inc. v. NRC Indus.*, 659 F. Supp. 3d 451, 462 (D.N.J. 2023) (citing *Campbell v. Pennsylvania Sch. Boards Ass'n*, 972 F. 3d 213, 218–19 (3d Cir. 2020)). Regarding the first prong of the "sham" analysis, the "objectively baseless" standard is analogized to the concept of "probable cause, as understood and applied in the commonlaw tort of wrongful civil proceedings." *PRE*, 508 U.S. at 62. "Probable cause to institute civil proceedings requires

no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication." *Id.* at 62–63 (internal quotation marks, citations, and alterations omitted). The first prong of the test, with its emphasis on the reasonable litigant, is concerned with the objective merits of the lawsuit at issue. *Id.* "Thus, if probable cause exists, [a court's] inquiry is at an end." *Campbell*, 972 F. 3d at 219. However, if the objective prong is met, "the fact that a suit may lack any objective merit is not itself determinative." *Id.* A court must then, under the second prong, "inquire into the plaintiff's subjective motivations for bringing suit." *Id.* (citation omitted). A court takes "this additional step to ascertain whether the actual motivation is to dragoon the 'governmental process' itself into use as a competitive tool," which "often means examining 'evidence of the suit's *economic* viability.'" *Id.* (citation omitted). "The difficulty of proving subjective motivation obviously 'places a heavy thumb on the scale' in favor of granting protection." *Id.* (citation omitted). "Only if these objective and subjective tests are satisfied is *Noerr-Pennington* protection lost and the suit permitted to proceed." *Id.* Here, the parties' dispute centers on the first prong. Specifically, the Celgene Defendants' motion to dismiss challenges the Insurer Plaintiffs' and MSP Plaintiffs' sham litigation allegations by contending that they have failed to plausibly allege that Celgene's patent infringement lawsuits were based on a theory of infringement or validity that is "objectively baseless"—in other words that no reasonable person would believe that the patent was infringed, valid, or enforceable. (Mov. Br. at 16–27).

Generally, a plaintiff seeking to show the sham litigation exception faces "an uphill battle." *Wellbutrin*, 868 F.3d at 147. In some respects, the hill is steeper "in the context of an ANDA case." *Id.* at 149. "Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement

or invalidity in the certification." *Id.* (citation omitted). Moreover, the number of lawsuits a brand-name drug manufacturer files will sometimes reveal little about its subjective motivation for suing because the Hatch-Waxman Act "incentivizes [brands] to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so." *Id.* at 157–58 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Further, when the theory of sham litigation is predicated on a claim that a patent is invalid, a plaintiff must account for the presumption of patent validity, which can only be overcome by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91, 95 (2011) (quoting 35 U.S.C. § 282). Given the presumption of patent validity and the burden on the patent challenger to prove invalidity by clear and convincing evidence, "it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." *Duke Univ., Allergan, Inc. v. Akorn, Inc.*, No. 18-14035, 2019 WL 4410284, at *7 (D.N.J. Sept. 16, 2019) (citing *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014)). This is particularly true where the patentee asserts claims "in a patent whose validity has not yet been litigated." *Id.* As such, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" cannot clear this hurdle on a motion to dismiss. *United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 15 (1st Cir. 2018); *see also Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, No. 18-1994, 2021 WL 3144897, at *12 (D.N.J. July 26, 2021), *aff'd*, No. 21-2608, 2022 WL 17546949 (3d Cir. Dec. 9, 2022) (stating that "[s]howing that the law or the facts are 'questionable or unfavorable at the outset' is not enough," to establish objective baselessness "nor is showing that the infringement claim 'would have been subject to a serious defense' or is doubtful" (citation omitted)).

a. The ’517 Patent

The Insurer Plaintiffs’ Allegations. The Insurer Plaintiffs allege that Celgene could not realistically expect to prevail in asserting any claims based on the ’517 Patent because (i) its fraudulent conduct would render the patent unenforceable; (ii) the patent is invalid as obvious; and/or (iii) the patent is invalid as not enabled based on testing by Celgene described in a declaration submitted to the European Patent Office. (Opp. Br. at 36). The Celgene Defendants argue that the Insurer Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity with respect to Celgene’s conduct in asserting the ’517 Compound Patent. (Mov. Br. at 17–19; Reply at 6–10). The Court will examine whether any of these allegations sufficiently plead the sham litigation exception to *Noerr-Pennington* immunity in turn. For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that they cannot.

First, as described above, the Insurer Plaintiffs allege that no reasonable litigant in Celgene’s shoes could expect to prevail in asserting any claims based on the ’517 Patent because that patent was procured by fraud. (Opp. Br. at 36). More specifically, the Insurer Plaintiffs reference their allegations, described above, that Celgene obtained the ’517 Patent by fraud during reexamination. (Humana Am. Compl. ¶¶ 259–76). The Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity. As already discussed above, the Insurer Plaintiffs have failed to allege sufficient facts to show that Celgene procured the ’517 Compound Patent through fraud on the USPTO. (*See supra* at 193–202). As such, for the same reasons, the Insurer Plaintiffs cannot plausibly allege that Celgene’s patent infringement suits asserting the ’517 Compound Patent were objectively baseless based on a theory that this patent was procured by fraud. *See Westlake Servs., LLC v. Credit Acceptance Corp.*, No. 15-7490, 2015 WL 9948723, at *9 (C.D. Cal. Dec. 7, 2015) (finding that, where plaintiffs failed to plead *Walker*

Process fraud, they likewise could not sufficiently allege that defendant engaged in sham litigation by asserting a patent that was allegedly procured by said fraud); *see also Pac. Biosciences of California, Inc.*, 2019 WL 668843, at *4.

Second, the Insurer Plaintiffs allege that Celgene could not realistically have expected to prevail in asserting any claims based on the '517 Patent because the patent is invalid as obvious over prior art, including the D'Amato Patents and Leibovich References that caused the examiner to revoke the '517 Patent during reexamination. (Opp. Br. at 36; Humana Am. Compl. ¶¶ 259–76). The Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity. As described above, during reexamination of the '517 Compound Patent, the USPTO rejected all of the claims of the '517 Patent as obvious over the D'Amato Patents in view of the Leibovich References. (Humana Am. Compl. ¶ 264). To overcome this rejection, Celgene's counsel submitted a request for reconsideration and attached a declaration from Celgene's then Chief Scientific Officer, Dr. Stirling, as support for its request, which demonstrated certain unexpected properties. (*Id.* ¶ 265). Though counsel for Celgene maintained that the D'Amato Patents and Leibovich References did not render the claims of the '517 Patent obvious, he contended that even if those references were deemed sufficient to establish obviousness, any such finding of obviousness was rebutted by the unexpected properties depicted in Dr. Stirling's Declaration. (*Id.* ¶ 268). Shortly thereafter, the USPTO issued a notice of intent to issue a reexamination certificate allowing the claims of the '517 Patent. (*Id.* ¶ 269). The Insurer Plaintiffs allege that Celgene could not realistically have expected to prevail in asserting any claims based on the '517 Patent because Celgene was only able to overcome the prior art obviousness rejections over the D'Amato Patents and Leibovich References during reexamination of the '517 Compound Patent by submitting the fraudulent Stirling Declaration. (*Id.* ¶¶ 259–76). Because Celgene could

only overcome those prior art obviousness rejections through fraud, the Insurer Plaintiffs assert that the '517 Patent is invalid as obvious. However, because of the presumption of patent validity, it will usually be a "rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." *Duke Univ.*, 2019 WL 4410284, at *7.[87] "[A]llegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" cannot clear this hurdle. *Novartis*, 902 F.3d at 15. As discussed above, the Court has already found the Insurer Plaintiffs' allegations of fraud as to the '517 Patent implausible. The Insurer Plaintiffs do not otherwise explain why it was objectively baseless for Celgene to believe that the '517 Patent's presumed validity could withstand an obviousness challenge over the D'Amato Patents and Leibovich References, when Celgene was able to successfully overcome those references during prosecution of the patent. As such, by alleging that the '517 Patent is obvious over the D'Amato Patents and Leibovich References, the Insurer Plaintiffs have done nothing more than assert that Celgene would have faced some kind of defense to its infringement litigation asserting that patent.

[87] Citing to the court's decision in *Teva Pharm. Indus., Ltd. v. Apotex, Inc.*, No. 07-5514, 2008 WL 3413862, at *6 (D.N.J. Aug. 8, 2008), the Insurer Plaintiffs and MSP Plaintiffs contend that because the presumption of patent validity speaks to who bears the evidentiary burden down the road, on a motion to dismiss, any presumption as to a patent's validity is not controlling to show objective baselessness to support allegations of sham litigation. (Opp. Br. at 35 n.129). However, *Teva* is distinguishable. In *Teva*, the plaintiff filed suit against the defendant for patent infringement and the defendant then filed a counterclaim for a violation of Section 2 of the Sherman Act, contending that the plaintiff's assertion of its patents was objectively baseless. *Teva*, 2008 WL 3413862, at *1. As the Celgene Defendants pointed out at oral argument, *Teva* is distinguishable from the present case because there the court was considering allegations of sham litigation as the patent dispute was unfolding. Accordingly, it may very well have been difficult for the Court to say on the pleadings and without discovery that the patentee's assertion of its patents in that case was not objectively baseless, where the underlying patent dispute between competitors was ongoing. (Tr. of Sept. 8, 2023 Oral Arg. at 124:8–13). That is not the case here. And under the circumstances of this case, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" are insufficient to plead sham litigation, particularly because of the presumption of patent validity. *Novartis*, 902 F.3d at 15. As the Seventh Circuit pointed out, "a separate antitrust suit by strangers to the patent litigation does not justify an effort to adjudicate by proxy what might have happened in the patent litigation, but didn't." *AbbVie* Inc., 42 F.4th at 714.

Such allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. *Duke Univ.*, 2019 WL 4410284, at * 7.[88]

Third, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail on its claims that the '517 Patent was valid, as the patent is invalid for failing to satisfy the enablement requirement based on testing Celgene described in a declaration submitted to the European Patent Office.[89] (Opp. Br. at 36). However, at oral argument, the Insurer Plaintiffs conceded that such allegations were not sufficient to support a theory of sham litigation. (Tr. of Sept. 8, 2023 Oral Arg. at 146:4–15). As such, the Court finds that these allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.[90]

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[88] The Insurer Plaintiffs also allege that Claim 10 of the '517 Patent, which claims lenalidomide, would have been obvious in light of two compounds, namely EM-12 and/or 4-aminothalidomide. They claim that these compounds were structurally similar to lenalidomide and were known to treat a variety of conditions. (Humana Am. Compl. ¶¶ 252–58). The Insurer Plaintiffs allege that a person of ordinary skill in the art would have been motivated to make small structural changes to these compounds, yielding the lenalidomide compound claimed by the '517 Patent and rendering it obvious. (*Id.*). At oral argument, the Insurer Plaintiffs clarified that the motivation to make structural changes to EM-12 and/or 4-aminothalidomide did not come from prior art that was separate and different from the D'Amato Patents and Leibovich References. Rather they clarified that this motivation came from the D'Amato Patents and Leibovich References. (Tr. of Sept. 8, 2023 Oral Arg. at 118:8–120:12). As described above, the Insurer Plaintiffs' allegations do not plausibly suggest that it was unreasonable for Celgene to expect that the '517 Patent's presumed validity could withstand an obviousness challenge over prior art, including the D'Amato Patents and Leibovich References, which Celgene was able to successfully overcome during prosecution of the patent. And regardless, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" are insufficient to plead sham litigation. *Novartis*, 902 F.3d at 15.

[89] The MSP Plaintiffs do not pursue this theory. (Tr. of Sept. 8, 2023 Oral Arg. at 138:22–139:10).

[90] In arguing that Celgene's conduct in asserting the '517 Patent was objectively baseless, the Insurer Plaintiffs and MSP Plaintiffs rely on the Third Circuit's decision in *AbbVie*. (Tr. of Sept. 8, 2023 Oral Arg. at 126:24–129:2). There, the Third Circuit upheld the district court's determination that a lawsuit was objectively baseless based on prosecution history estoppel. After AbbVie's patent application was denied, AbbVie amended its patent claim to include only one "penetration enhancer" chemical rather than the 24 it had included the first time. *AbbVie*, 976 F.3d at 366. The alleged infringer in that case used a penetration enhancer chemical that was included among the original 24 chemicals, but which AbbVie had specifically *removed* from its amended patent application. The alleged infringer pointed out in its Paragraph IV notice that it had used one of the penetration enhancers that was removed from the amended patent application, and that AbbVie was estopped from asserting infringement based on that no-longer-claimed chemical. *Id.* The Third Circuit found that any reasonable litigant in AbbVie's position should have realized that it had no reasonable expectation of prevailing in its infringement suit. *Id.* at 366–68. Here, there is no such clear-cut reason that Celgene should have been certain that its lawsuits asserting the '517 Patent would fail, as described above.

The MSP Plaintiffs' Allegations. The MSP Plaintiffs allege that Celgene could not realistically have expected to prevail in asserting any claims based on the '517 Patent because (i) the patent was procured by fraud since the USPTO was not aware of key prior art when the '517 Patent was granted and (ii) because the patent is invalid as obvious in light of research conducted long before Celgene began its effort to bring Revlimid to market. (MSP SAC ¶¶ 264–65). The Celgene Defendants argue that the MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity with respect to Celgene's conduct in asserting the '517 Compound Patent. (Mov. Br. at 17–19; Reply at 6–10). For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that the MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity.

First, as described above, the MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on the '517 Patent because that patent was procured by fraud. More specifically, the MSP Plaintiffs generally allege that the '517 Patent was procured by fraud because the USPTO was not aware of key prior art when the '517 Patent was granted. (MSP SAC ¶¶ 264–65). The Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity. As already discussed above, the MSP Plaintiffs have failed to allege sufficient facts to show that Celgene procured the '517 Compound Patent through fraud on the USPTO. As such, for the same reasons, the MSP Plaintiffs cannot plausibly allege that Celgene's patent infringement suits asserting the '517 Compound Patent were objectively baseless on a theory that the patent was procured by fraud. *See Westlake Servs., LLC*, 2015 WL 9948723, at *9; *Pac. Biosciences of California, Inc.*, 2019 WL 668843, at *4.

Second, the MSP Plaintiffs allege that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because the patent is invalid as obvious in light of

research conducted before the '517 Patent's priority date. (MSP SAC ¶¶ 264–65). Such conclusory allegations are plainly insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. As already stated, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. *Novartis*, 902 F.3d at 15. Nor are allegations that patents are "weak" or are likely to be invalidated sufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. *See Braintree Labs., Inc. v. Schwarz Pharma, Inc.*, 568 F. Supp. 2d 487, 497 (D. Del. 2008) ("Even a potentially 'weak' patent enjoys a presumption of validity."). Here, the MSP Plaintiffs have done nothing more than allege that the '517 Patent was weak and likely to be invalidated. More specifically, they only generally allege that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because the patent is invalid as obvious in light of research conducted before the '517 Patent's priority date. But such conclusory allegations do not plausibly suggest that it was objectively baseless for Celgene to expect that the '517 Patent's presumed validity could withstand an obviousness challenge. *Duke Univ.*, 2019 WL 4410284, at *7. This is particularly true given that the MSP Plaintiffs do not identify which prior art rendered the '517 Patent invalid and do not explain how that prior art renders the claims of the '517 Patent obvious. Further, to the extent that the MSP Plaintiffs generally allege that Celgene's conduct in asserting the '517 Patent was objectively baseless and a sham, such conclusory legal allegations are also insufficient to overcome *Noerr-Pennington* immunity. *Picone v. Shire PLC*, No. 16-12396, 2017 WL 4873506, at *7 (D. Mass. Oct. 20, 2017) (finding that the plaintiffs' allegations that patents were weak and likely to be invalidated insufficient to plead sham litigation). Accordingly, these allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.

In sum, in-so-far as the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act by bringing sham patent infringement lawsuits against various generic competitors to enforce the '517 Patent, the Court finds that their allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. As such, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.[91]

b. The Method of Treatment Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs next allege that no reasonable litigant in Celgene's shoes could realistically have expected to prevail on its infringement allegations as to the Method of Treatment Patents because: (i) the '740 Method of Treatment Patent is unenforceable due to fraud and invalid as obvious in light of prior art, including prior art identified by the examiner before Celgene's fraud, which also renders two of Celgene's other method of treatment patents invalid (including the '717 Patent and the '120 Patent); and (ii) the patents claiming methods of treating cancer are obvious based on prior art. (Opp. Br. at 38). The Celgene Defendants argue that the Insurer Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity with respect to Celgene's conduct in asserting its Method of Treatment Patents. (Mov. Br. at 19–21; Reply at 10–12). For the reasons set forth below, the Court agrees with the Celgene Defendants.

First, as described above, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could have expected to prevail in asserting any claims based on the '740 Method of Treatment Patent because Celgene's fraudulent conduct during the prosecution of that patent

[91] In their Opposition Brief, the Insurer Plaintiffs and MSP Plaintiffs suggest that Celgene could not realistically expect to prevail in asserting any claims based on the '517 Patent because the patent was not infringed. (Opp. Br. at 36). Nevertheless, the Insurer Plaintiffs and MSP Plaintiffs do not provide any explanation or allegations as to why it was objectively baseless for Celgene to expect that its '517 Patent was infringed. (*See generally* Opp. Br.). And the Insurer Plaintiffs and MSP Plaintiffs cannot plead the sham litigation exception to *Noerr-Pennington* immunity merely by alleging, in a conclusory fashion, that this patent was not infringed. *Wellbutrin*, 868 F.3d at 149; *Takeda*, 2021 WL 3144897, at *12.

would render the patent unenforceable.[92] (Opp. Br. at 38; Humana Am. Compl. ¶¶ 313–21). The Celgene Defendants argue that these allegations fail to state a claim because the '740 Method of Treatment Patent was not obtained by fraud. (Mov. Br. at 20–21; Reply at 11). The Court agrees with the Celgene Defendants. As already recounted above, the Insurer Plaintiffs have failed to allege sufficient facts to show that Celgene procured the '740 Method of Treatment patent through fraud on the USPTO. (*See supra* at 203–08). As such, for the same reasons, the Insurer Plaintiffs cannot plausibly allege that Celgene's patent infringement suits asserting the '740 Method of Treatment Patent were objectively baseless because that patent was procured by fraud. *See Westlake Servs., LLC*, 2015 WL 9948723, at *9. In fact, at oral argument the Insurer Plaintiffs conceded that if the Court were to find that they failed to adequately allege *Walker Process* fraud based on Celgene's conduct during the prosecution of the '740 Method of Treatment Patent, they also could not plausibly allege that Celgene's patent infringement suits asserting the '740 Patent were objectively baseless because that patent was procured by fraud. (Tr. of Sept. 8, 2023 Oral Arg. at 152:24–153:6).

The Insurer Plaintiffs also claim that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on the '740 Method of Treatment Patent because that patent is invalid as obvious based on prior art identified by the examiner before Celgene's alleged fraud. (Opp. Br. at 38). The Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity. As described above, during the prosecution of the '740 Patent, the examiner rejected the claims of the patent as anticipated or obvious over a number of prior art references. (Humana Am. Compl. ¶¶ 315 & 320). According to the Insurer Plaintiffs, Celgene was only able to overcome those prior art rejections by submitting the Zeldis Declarations, which

[92] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations.

provided that the inventor conceived of the invention disclosed in the '740 Patent earlier than any of those references. (*Id.* ¶¶ 316–21). However, while the Insurer Plaintiffs claim that the Zeldis Declarations were fraudulent, as recounted above, they have failed to allege sufficient facts to support such an inference. (*See supra* at 203–08). As such, the Insurer Plaintiffs' allegations do not plausibly suggest that it was objectively baseless for Celgene to expect that the '740 Patent's presumed validity could withstand an obviousness challenge over prior art that Celgene was able to successfully overcome during prosecution of the patent. *See Duke Univ.*, 2019 WL 4410284, at * 7. In fact, at oral argument the Insurer Plaintiffs conceded that if the Court were to find that they failed to adequately allege *Walker Process* fraud based on Celgene's conduct during the prosecution of the '740 Method of Treatment, they could not plausibly allege that it was objectively baseless for Celgene to expect that the '740 Patent's presumed validity could withstand an obviousness challenge over prior art that Celgene was able to successfully overcome during prosecution of the patent. (Tr. of Sept. 8, 2023 Oral Arg. at 153:8–18).

The Insurer Plaintiffs also argue that no reasonable litigant in Celgene's shoes could expect to prevail in asserting any claims based on its Method of Treatment Patents because the same prior art identified by the examiner before Celgene's alleged fraud in procuring the '740 Method of Treatment Patent also renders two of Celgene's other method of treatment patents regarding myelodysplastic syndromes invalid, including the '717 Patent and '120 Patent. (Opp. Br. at 38).[93] However, the Amended Complaint at no point alleges that the '717 Patent and the '120 Patent

[93] In their Amended Complaint the Insurer Plaintiffs also allege that Dr. Reddy's previewed winning invalidity arguments regarding the '740 Patent, '717 Patent, and '120 Patent in proceedings in front of the PTAB. (Humana Am. Compl. ¶ 384). More specifically, they allege that Dr. Reddy's introduced two press releases bearing dates which would have invalidated the '740 Patent, '717 Patent, and '120 Patent. (*Id.*). While the Insurer Plaintiffs acknowledge that the PTAB was forced to deny institution of IPR with respect to these patents because Dr. Reddy's could not prove that the press releases were publicized on the date that appeared on the face of the documents, they allege that this is "an easily correctible evidentiary issue that could be overcome in this litigation." (*Id.*; Opp. Br. at 39). Nevertheless, at oral argument, the Insurer Plaintiffs conceded that they are not attempting to plead the sham litigation exception to *Noerr-Pennington* immunity based on these allegations. (Tr. of Sept. 8, 2023 Oral Arg. at 154:20–155:1).

were invalid as obvious based on the prior art identified by the examiner before Celgene submitted the allegedly fraudulent Zeldis Declarations during the prosecution of the '740 Patent. (*See* Humana Am. Compl. ¶¶ 315 & 320). Accordingly, any such argument does not appear on the face of the Amended Complaint. And the Insurer Plaintiffs admitted as much at oral argument. (Tr. of Sept. 8, 2023 Oral Arg. at 153:25–154:4). As such, regardless of the merits of this argument, the Insurer Plaintiffs fail to plausibly allege that it was objectively baseless for Celgene to expect that the presumed validity of the '717 Patent and '120 Patent could withstand an obviousness challenge over prior art identified by the examiner before Celgene's alleged fraud in procuring the '740 Method of Treatment Patent. Further, at oral argument, the Insurer Plaintiffs conceded that such allegations could not plead the sham litigation exception to *Noerr-Pennington* immunity. (*Id.* at 154:5–8). Accordingly, the Court finds that the Insurer Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity as to the '740, '717, and '120 Method of Treatment Patents.

Second, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the Method of Treatment Patents, including the '569, '498, '095, and '622 Patents, because those patents claiming methods of treating cancer are obvious based on prior art. (Opp. Br. at 38; Tr. of Sept. 8, 2023 Oral Arg. at 158:8–24). More specifically, they allege that these patents, which claim the administration of lenalidomide in combination with a steroid called dexamethasone in specific dosing regimens, are subject to strong invalidity challenges, including obviousness, because it was well known in the prior art that lenalidomide in combination with steroids such as dexamethasone could be used to treat cancers. (Humana Am. Compl. ¶¶ 327–28). The Insurer Plaintiffs allege that during prosecution, to overcome the USPTO's rejections for obviousness, Celgene submitted findings

that it argued showed it had determined that there were unexpected results in its claimed method of treating cancer. (*Id.* ¶ 328). For example, during prosecution of the '569 Patent, Celgene allegedly submitted numerous publications to show that its claimed method of treatment had surprising and unexpected effects in treating multiple myeloma patients in comparison to the prior art. (*Id.*). However, because the publications submitted to show those unexpected results post-dated the claimed invention, the Insurer Plaintiffs assert that they did not support a finding of patentability at the time of the invention. (*Id.* ¶ 329).[94] In moving to dismiss these allegations, the Celgene Defendants contend that well-established law provides that evidence of unexpected results may be used to rebut a case of prima facie obviousness even if that evidence was obtained after the patent's filing or issue date, and so it was objectively reasonable for Celgene to rely on these results. (Mov. Br. at 20 (citing *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011)). The Court agrees and finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity. As the Celgene Defendants point out (Mov. Br. at 20), the Federal Circuit has made clear "that evidence of unexpected results may be used to rebut a case of *prima facie* obviousness even if that evidence was obtained after the patent's filing or issue date." *Genetics Inst., LLC* 655 F.3d at 1307; *see also Sanofi–Aventis Deutschland GmbH v. Glenmark Pharm., Inc.*, 748 F.3d 1354, 1360 (Fed. Cir. 2014) ("Glenmark also argues that later-discovered benefits cannot be considered in an obviousness analysis . . . . That is incorrect; patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest."). Accordingly, as the Insurer Plaintiffs conceded at oral argument, the mere fact that Celgene submitted to the USPTO reports on the unexpectedly good results of the invention of the '569 Patent that post-dated the date of

[94] The MSP Plaintiffs' Second Amended Complaint does not contain these allegations.

invention does not indicate that this patent or the other Method of Treatment Patents including the '498, '095, and '622 Patents are invalid as obvious. (Tr. of Sept. 8, 2023 Oral Arg. at 159:16–160:6). The Insurer Plaintiffs provide no other allegations to indicate that Celgene's unexpected results could not overcome any findings of obviousness. As such, the Insurer Plaintiffs' allegations do not plausibly suggest that it was objectively baseless for Celgene to expect that the presumed validity of the Method of Treatment Patents, including the '569, '498, '095, and '622 Patents, could withstand an obviousness challenge over prior art that Celgene was able to successfully overcome during prosecution of the patents with evidence of unexpected results. *See Duke Univ.*, 2019 WL 4410284, at * 7. Further, though the Insurer Plaintiffs generally allege that the '569, '498, '095, and '622 Patents are obvious because it was well known in the prior art that lenalidomide in combination with steroids such as dexamethasone could be used to treat cancers, they have done nothing more than allege that those patents were weak and were likely to be found obvious. (Humana Am. Compl. ¶¶ 327–28). Such allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.[95] *See Picone*, 2017 WL 4873506, at *7.

The MSP Plaintiffs' Allegations. The MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act, in part, by bringing sham patent infringement lawsuits against various generic competitors to enforce its method of treatment patents, including the '740 Patent, '717 Patent, '120 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, '622 Patent, '363 Patent, and '929 Patent. (MSP SAC ¶¶ 367–75 & 382–469). Other than generally alleging that Celgene's

[95] The Insurer Plaintiffs allege that though Celgene improperly obtained sixteen method of treatment patents, many of those patents related to uses that were susceptible to Section viii carveouts. (Humana Am. Compl. ¶ 322). In moving to dismiss these allegations, the Celgene Defendants assert that even the Insurer Plaintiffs concede that those generic manufacturers that submitted Section viii statements, including Lotus, Dr. Reddy's, and Natco, could not carve out all relevant uses of their proposed generic drug that would be covered by Celgene's Method of Treatment Patents and as a result would infringe certain of those patents. (Mov. Br. at 21). And they argue that citing non-infringement arguments "hardly states a claim for sham litigation." (*Id.*). Nevertheless, at oral argument, the Insurer Plaintiffs conceded that they are not attempting to plead the sham litigation exception to *Noerr-Pennington* immunity based on these allegations. (Tr. of Sept. 8, 2023 Oral Arg. at 160:8–15).

conduct in asserting these patents against its competitors was a sham because those patents were invalid and/or not infringed, the MSP Plaintiffs do not provide any specific allegations regarding why no reasonable litigant in Celgene's shoes could realistically expect to prevail in asserting any claims based on these Method of Treatments Patents. (*See id.*). Such conclusory legal allegations are plainly insufficient to plausibly show that Celgene's conduct in asserting its Method of Treatment Patents was objectively baseless. *See Picone*, 2017 WL 4873506, at *6 (stating that in determining whether plaintiffs have plausibly alleged the sham litigation exception to *Noerr-Pennington* immunity "the Court does not credit the purely conclusory legal allegations that the '290 Patent was 'objectively baseless' or that Shire engaged in 'sham patent litigation.'"); *Wellbutrin*, 868 F.3d at 149 ("[A]n infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification."). Further, to the extent the MSP Plaintiffs generally allege that Celgene's conduct in asserting the Method of Treatment Patents was objectively baseless, because those patents were weak, such generalized allegations are not sufficient to plausibly suggest that it was objectively baseless for Celgene to expect that the presumed validity of the Method of Treatment Patents could withstand a validity challenge. *See Braintree Labs., Inc*, 568 F. Supp. 2d at 497.[96]

In sum, in-so-far as the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act in part by bringing sham patent infringement lawsuits against various generic competitors to enforce its Method of Treatment Patents, as listed above, the Court finds

[96] In their Opposition Brief, the Insurer Plaintiffs and MSP Plaintiffs suggest that Celgene could not realistically expect to prevail in asserting any claims based on the Method of Treatment Patents because those patents were not infringed. (Opp. Br. at 38). Nevertheless, the Insurer Plaintiffs and MSP Plaintiffs do not provide any explanation or allegations as to why it was objectively baseless for Celgene to expect that its Method of Treatment Patents were infringed beyond those discussed. (*See generally* Opp. Br.). And the Insurer Plaintiffs and MSP Plaintiffs cannot plead the sham litigation exception to *Noerr-Pennington* immunity merely by alleging, in a conclusory fashion, that those patents were not infringed. *Wellbutrin*, 868 F.3d at 149; *Takeda*, 2021 WL 3144897, at *12.

that their allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. As such, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

c. The Polymorph Patents

The Insurer Plaintiffs' Allegations. The Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically have expected to prevail on its infringement allegations as to its Polymorph Patents because: (i) the '357 Patent, the '598 Patent, and the '219 Patent were invalid as anticipated and/or obvious; and (ii) the '800 Patent and the '217 Patent were invalid as anticipated and/or obvious and were invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40). The Celgene Defendants argue that the Insurer Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity based on Celgene's conduct in asserting its Polymorph Patents. (Mov. Br. at 21–23; Reply at 12–13). The Court will examine whether any of these allegations sufficiently plead the sham litigation exception to *Noerr-Pennington* immunity in turn. For the reasons set forth below, the Court agrees with the Celgene Defendants and finds that they cannot.

First, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its Polymorph Patents because the '357 Patent, '598 Patent, and '219 Patent were invalid as anticipated and/or obvious. (Opp. Br. at 40–41). More specifically, the Insurer Plaintiffs allege that Celgene's filings in the course of defending its European patent, EP '682, in proceedings before the EPO, indicate that the '357 Patent, '598 Patent, and '219 Patent are invalid. As recounted above, on November 2, 2011, the EPO granted Celgene EP '682, which claims Form A of lenalidomide. (Humana Am. Compl. ¶ 288). On January 8, 2012, Mylan filed a Notice of Opposition with the EPO requesting that the

EPO revoke Celgene's European Patent, EP '682, as lacking novelty in light of Celgene's (US) '517 Compound Patent. (*Id.* ¶ 290). Mylan submitted testing indicating that if the steps in Example 1 of the '517 Patent are carried out, it results in the same Form A lenalidomide polymorph as claimed by EP '682, rendering EP '682 invalid as anticipated. (*Id.*). On February 8, 2012, Teva filed a Notice of Opposition, similarly requesting the revocation of EP '682 on the basis of lack of novelty in light of the '517 Patent. (*Id.* ¶ 291). Like Mylan, Teva also submitted testing indicating that if the steps in Example 1 of the '517 Patent are carried out, it results in the same Form A lenalidomide polymorph as claimed by EP '682, rendering EP '682 invalid as anticipated. (*Id.*). To defend the validity of its European Patent, Celgene filed a declaration asserting that when Celgene's own expert was asked to synthesize lenalidomide by following the procedures of Example 1 of the '517 Patent he did not obtain lenalidomide at all. (*Id.* ¶ 292). As such, Celgene argued that its European polymorph patent could not be anticipated by its U.S. '517 Patent. (*Id.*). On June 24, 2015, the EPO issued a decision revoking EP '682 based on the rationale that Form A of lenalidomide claimed by EP '682 was anticipated by the '517 Patent. (*Id.* ¶ 293). Here, the Insurer Plaintiffs allege that the testing submitted by Mylan and Teva to the EPO indicated that the polymorphic Form A of lenalidomide was necessarily produced if one followed the teachings of the '517 Compound Patent. (Opp. Br. at 40–41). As such, the Insurer Plaintiffs contend that those results would render any patent claiming Form A of lenalidomide—including the '357 Patent, '598 Patent, and '219 Patent—anticipated or obvious in light of the'517 Patent. (*Id.*). And because Mylan and Teva's testing indicated that the '357 Patent, '598 Patent, and '219 Patent were anticipated or obvious, the Insurer Plaintiffs contend that no reasonable litigant in Celgene's shoes could have reasonably expected to succeed in enforcing such invalid patents. (*Id.*). In moving to dismiss these allegations, the Celgene Defendants contend that the Insurer Plaintiffs' citations to

foreign proceedings on foreign patents have "no bearing on whether enforcement of U.S. patents under U.S. law was a sham." (Mov. Br. at 22). For the following reasons, the Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity.

To qualify for patent protection, an innovation must fulfill the novelty requirement as set forth in 35 U.S.C. § 102. Consistent with this novelty requirement, "patent law has long required that an innovation not be anticipated by the prior art in the field." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149–50 (1989). "A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *see also Hazani v. United States ITC*, 126 F.3d 1473, 1477 (Fed. Cir. 2003) (explaining that prior art renders a patented invention anticipated if it discloses every feature of the claimed invention, either explicitly or inherently). The obviousness requirement, arguably a more subtle inquiry, provides that a patent may not be obtained, even if an invention is not identical to a piece of prior art, if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *Minkin v. Gibbons P.C.*, No. 08-2451, 2010 WL 5419004, at *5 (D.N.J. Dec. 23, 2010), *aff'd,* 680 F.3d 1341 (Fed. Cir. 2012) (citing 35 U.S.C. § 103(a)).

As already stated, because of the presumption of patent validity, it will usually be a "rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." *Duke Univ.*, 2019 WL 4410284, at *7 (quoting *Tyco Healthcare Grp. v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014)). This is particularly true where a patentee asserts claims in a patent whose

validity has not yet been litigated. *Id.* at *8. As such, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" cannot clear this hurdle. *Novartis,* 902 F.3d at 15. Here, the Insurer Plaintiffs' allegations only demonstrate that Celgene would have faced a serious defense to its infringement litigations asserting the '357 Patent, '598 Patent, and '219 Patent. More specifically, as alleged by the Insurer Plaintiffs, because the testing submitted by Mylan and Teva to the EPO indicated that the polymorphic Form A of lenalidomide was necessarily produced if one followed the teachings of the '517 Compound Patent, it is certainly possible that the'517 Patent would render any patent claiming Form A of lenalidomide—including the '357 Patent, '598 Patent, and '219 Patent—anticipated or obvious. (Humana Am. Compl. ¶¶ 290–91). However, at the same time, as the Insurer Plaintiffs allege, to rebut those testing results Celgene filed its own declaration asserting that when Celgene's expert was asked to synthesize lenalidomide by following the procedures of Example 1 of the '517 Patent he did not obtain lenalidomide at all. (*Id.* ¶ 292). As such, Celgene argued that its European polymorph patent could not be anticipated by the '517 Patent. (*Id.*). While the EPO ultimately revoked EP '682 and found that Celgene failed to present sufficient evidence to rebut Mylan and Teva's testing results (*id.* ¶ 293), the Court cannot plausibly infer that it was objectively unreasonable for Celgene to expect that the presumed validity of the '357 Patent, '598 Patent, and '219 Patent claiming Form A of lenalidomide could withstand an obviousness and/or anticipation challenge over the inherent teachings of the '517 Patent when Celgene allegedly had testing indicating that lenalidomide was not produced at all if one followed the teachings of the '517 Patent. *See Novartis,* 902 F.3d at 15 ("[T]he complaints' mere allegations that 'the two techniques Novartis described in its patent application . . . were commonly known methods for developing alternate crystalline forms at the time' and that a pharmaceutical chemist

of ordinary skill would have been motivated to develop an advantageous crystalline form of imatinib mesylate are insufficient to allege plausibly that Novartis was unreasonable in expecting that Patent '051's presumed validity could withstand an obviousness challenge."). In fact, though the Insurer Plaintiffs contend that the testing submitted by Mylan and Teva to the EPO necessarily indicated that the '357 Patent, '598 Patent, and '219 Patent were anticipated and/or obvious in light of the'517 Patent, they acknowledge that the declaration submitted by Celgene to the EPO indicated that Celgene had testing to rebut those findings. (Tr. of Sept. 8, 2023 Oral Arg. at 144:5–10; Opp. Br. at 41 n. 149). In other words, as the Insurer Plaintiffs themselves stated, the proceedings before the EPO amounted to a "battle of the experts." (Tr. of Sept. 8, 2023 Oral Arg. at 144:5–10). While this battle of the experts demonstrates that Celgene would have faced a serious defense to its infringement litigations asserting the '357 Patent, '598 Patent, and '219 Patent, it does not plausibly show that Celgene's conduct in asserting those patents was objectively baseless. *See Louisiana Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, No. 19-14146, 2021 WL 4988523, at *9 (D.N.J. Oct. 27, 2021) (finding that plaintiffs failed to plead the sham litigation exception to *Noerr-Pennington* immunity where they could not identify a "clear-cut reason that [patentee] should have been certain that its lawsuit would fail.").

This is particularly true given that, as the Celgene Defendants point out, the Insurer Plaintiffs' theory of invalidity as to the '357 Patent, '598 Patent, and '219 Patent rests on the principle of inherency, which is a high standard that requires a showing that the claimed Form A of lenalidomide would *necessarily* have resulted after following the teachings of the '517 Patent. (Reply at 12–13). More specifically, it is well-settled that a prior art reference may anticipate a patent claim when the claim limitations not expressly found in that reference are nonetheless inherent in it. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). To show

inherent anticipation, the patent challenger must demonstrate that the claim limitation said to be inherent in the prior art is "*necessarily* present in the prior art, not merely *probably* or *possibly* present." *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003) (emphasis added). Likewise, "inherency may supply a missing claim limitation in an obviousness analysis." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194–95 (Fed. Cir. 2014). Here, as the Celgene Defendants assert, the Insurer Plaintiffs' theory of invalidity as to the '357 Patent, '598 Patent, and '219 Patent rests on an argument of inherency—that even though the '517 Patent may not have expressly disclosed Form A of lenalidomide—that polymorphic form of lenalidomide would necessarily have been produced after following the teachings of the '517 Patent rendering the '357 Patent, '598 Patent, and '219 Patent invalid as anticipated or obvious. However, given that any challenger would have needed to show that Form A of lenalidomide was necessarily, and not just probably or possibly, produced after following the teachings of the '517 Patent to show that the '357 Patent, '598 Patent, and '219 Patent were invalid as anticipated or obvious, the Court cannot say that it was objectively unreasonable for Celgene to expect that the presumed validity of the '357 Patent, '598 Patent, and '219 Patent could withstand an obviousness and/or anticipation challenge over the inherent teachings of the '517 Patent. This is particularly true given that Celgene allegedly performed testing indicating that lenalidomide was not produced if one followed the teachings of the '517 Patent. (Humana Am. Compl. ¶ 292). Accordingly, these allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.

Second, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because, based on Celgene's successful arguments in a *Markman* proceeding, the '800 Patent and '217 Patent are invalid for failing to satisfy the definiteness, written description, and

enablement requirements. (Opp. Br. at 40–41). More specifically, after Celgene asserted the '800 Patent against Natco in litigation, Natco argued that the term "hemihydrate" as appearing in the '800 Patent required an exact water to compound ratio of 0.5 to 1. (Humana Am. Compl. ¶ 358). Celgene, by contrast, argued that "hemihydrate," as used in the patent, implied an *approximate*, rather than exact, ratio. (*Id.*). In the court's *Markman* Opinion, the court adopted Celgene's proposed definition, reading "hemihydrate" as a term of approximation. (*Id.* ¶ 359). With the gloss of the term of "approximately" applied to "hemihydrate," the Insurer Plaintiffs allege that the '800 Patent was invalid for indefiniteness, lack of written description, and lack of enablement because (i) a person of ordinary skill would be unable to determine the scope of the patent, (ii) the patent did not disclose or suggest to a person of ordinary skill in the art that the patentee was in possession of other hemihydrated forms of lenalidomide, and (iii) the patent did not disclose how to make other hemihydrated forms of lenalidomide. (*Id.* ¶ 360). Because the '217 Patent also includes the term "hemihydrate," the Insurer Plaintiffs allege that it is invalid for the same reasons. (*Id.* ¶ 299). In moving to dismiss these allegations, the Celgene Defendants point out that the court ruled in Celgene's favor during this *Markman* hearing. (Mov. Br. at 21). They assert that even if Celgene's victory backfired by opening the door to new invalidity defenses, Celgene could not have divined the outcome of claim construction, let alone all resulting implications before filing suit. (*Id.* at 22). As such, they assert that Celgene's conduct in asserting those patents could not have been objectively baseless. The Court finds that these allegations fail to plead the sham litigation exception to *Noerr-Pennington* immunity.

An "essential" inquiry in determining whether a suit was a sham is not whether the suit ultimately succeeds, but rather, whether it was objectively baseless "at the time it was filed." *Duke Univ.*, 2019 WL 4410284, at *8 (citing *Wellbutrin*, 868 at 148). "[W]hen the antitrust defendant

has lost the underlying litigation, a court must resist the . . . temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE*, 508 U.S. at 60 n.5 (internal quotation marks and citation omitted). In *Wellbutrin*, when deciding whether a court's decision on claim construction should bear on whether the patent infringement suit was objectively baseless at the outset, the Third Circuit emphasized that "[w]hile it is no doubt important to think about possible constructions for patent claims before filing a case, it would be unfair to require parties to divine the outcome of claim construction before filing." *Wellbutrin*, 868 F.3d at 151 n. 22. The Third Circuit explained that this "is especially true in the Hatch-Waxman context, where many details about the potentially infringing drug (details that could shape a plaintiff's claim construction position) cannot be known at the time a suit is filed and where there are congressionally designed pressures to file suit quickly." *Id.* As such, the Third Circuit declined to find that the defendant's conduct in filing a patent infringement suit amounted to a sham in that case even where the defendant's claim construction arguments were ultimately unsuccessful, because doing so would undermine the operation of Hatch-Waxman. *Id.*

Here, the Insurer Plaintiffs argue that there was no scenario in which a reasonable litigant in Celgene's shoes could have realistically expected to prevail on its infringement allegations as to its '800 Patent—no matter the outcome of claim construction. More specifically, they contend that "Celgene was stuck in a catch-22 of its own making;" either the '800 Patent claimed an exact lenalidomide to water ratio (as Natco argued in claim construction), in which case no reasonable litigant in Celgene's position would have realistically expected to prevail in its allegations that Natco's generic lenalidomide infringed the '800 Patent; or the patent claimed an approximate ratio of lenalidomide-to-water (as Celgene successfully argued in claim construction), in which case no

reasonable litigant in Celgene's position would have realistically expected to prevail in its allegations that the patent was valid. (Opp. Br. at 41). These allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.

To start, as the Celgene Defendants point out and as the Third Circuit emphasized in *Wellbutrin*, "[w]hile it is no doubt important to think about possible constructions for patent claims before filing a case" Celgene is not expected to have "divine[d] the outcome of claim construction," let alone all resulting implications of claim construction "before filing." *Wellbutrin*, 868 F.3d at 151 n.22; (Mov. Br. at 22). Accordingly, the fact that Celgene ultimately pursued a claim construction that may have backfired and subjected the '800 Patent to new invalidity challenges does not necessarily show that its suits asserting that patent were objectively baseless at the time they were filed. *See PRE*, 508 U.S. at 60 n.5.

Nevertheless, the Insurer Plaintiffs contend that there was no scenario in which a reasonable litigant in Celgene's shoes could have realistically expected to prevail on its infringement allegations as to its '800 Patent—no matter the outcome of claim construction. (Opp. Br. at 41). On the one hand, as the Insurer Plaintiffs contend, it might certainly be true that Celgene would have had a more difficult time in demonstrating infringement had it argued that the '800 Patent claimed an exact lenalidomide-to-water ratio, as Natco ended up doing during claim construction. On the other hand, it is also possible that Celgene would have had a more difficult time in showing that its patents were valid if it argued that the '800 Patent claimed an approximate ratio of lenalidomide-to-water, as it ended up doing in claim construction. In fact, patentees often have to face the difficult decision of whether to argue for a broad claim construction for infringement purposes or for a narrower claim construction to guard against a finding of patent invalidity and the Insurer Plaintiffs conceded as much. *See, e.g.*, *Liebel–Flarsheim Co. v. Medrad*,

Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) (explaining that an infringement plaintiff must "beware of what [it] asks for" since a broad claim construction for infringement purposes may ultimately result in a determination of patent invalidity (internal quotation marks omitted)); (Tr. of Sept. 8, 2023 Oral Arg. at 173:1–16 (acknowledging that "it is very *classically* the case in patent law that a patentee is in a difficult situation" with respect to deciding whether to argue for a broad claim construction or for a narrower claim construction (emphasis added))). The fact that such a decision involves difficult tradeoffs does not plausibly show that it was objectively baseless for Celgene to believe that it could prevail in its suits asserting the '800 Patent. Rather, those allegations at most only indicate that Celgene would have faced a serious defense in its suits asserting the '800 Patent, regardless of the claim construction position it took. And the Insurer Plaintiffs conceded as much. (Tr. of Sept. 8, 2023 Oral Arg. at 174:3–20). As stated above, "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" are not sufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. *Novartis*, 902 F.3d at 15; *Janssen Biotech, Inc.*, 2021 WL 4988523, at *9.

The Insurer Plaintiffs' allegations regarding the '217 Patent are similarly implausible. More specifically, the Insurer Plaintiffs allege that because the '217 Patent also includes the term "hemihydrate," it faces the same defects as the '800 Patent. (Humana Am. Compl. ¶ 299). The Court again disagrees.[97] The fact that Celgene may have faced a serious defense to any litigation

[97] The Insurer Plaintiffs also point out that during claim construction, Dr. Reddy's argued that the term "crystalline" as appearing in the '800 and '217 Polymorph Patents did not encompass amorphous structures, such as its generic product. (Humana Am. Compl. ¶¶ 380–82). They allege that though Celgene initially opposed Dr. Reddy's construction, it resolved its dispute with Dr. Reddy's, paving the way for Dr. Reddy's to argue that its patents did not infringe on those Polymorph Patents. (*Id.* ¶ 382; *see also* MSP SAC ¶ 269). To the extent the Insurer Plaintiffs or MSP Plaintiffs rely on such allegations to support a theory of sham litigation, any such attempt fails. As described above, "[w]hile it is no doubt important to think about possible constructions for patent claims before filing a case" Celgene is not expected to have "divine[d] the outcome of claim construction," let alone all resulting implications of claim construction "before filing." *Wellbutrin*, 868 F.3d at 151 n.22. As such, the mere fact that Celgene chose not to oppose Dr. Reddy's claim construction during litigation does not plausibly indicate that its suits asserting the Polymorph Patents were objectively baseless at the time they were filed.

asserting the '217 Patent, regardless of the claim construction position it took with respect to the term hemihydrate appearing in that patent, is not sufficient to strip it of *Noerr-Pennington* immunity. *Novartis*, 902 F.3d at 15.[98]

Third, the Insurer Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically have expected to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because those patents were invalid as obvious and/or anticipated. (Opp. Br. at 40). More specifically, they allege that the '800 and '217 Patents were "obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent[s]. Celgene's failure provides an independent basis for invalidity." (Humana Am. Compl. ¶ 300). They further allege that "[t]hese polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity." (*Id.*). Such conclusory allegations are plainly insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. The Insurer Plaintiffs have done nothing more than allege that the '800 Patent and '217 Patent were weak and were likely to be invalidated. More specifically, they only generally allege that the '800 and '217 Patents were "obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent[s]" and are "obvious variants of the composition of matter patent, adding a further basis for invalidity." (*Id.*). But such conclusory allegations do not plausibly suggest that it was objectively baseless for Celgene to expect that the presumed validity of the '800 and '217 Patents could withstand an anticipation and/or obviousness challenge. *Duke Univ.*, 2019 WL 4410284, at *7; *Braintree Labs., Inc.*, 568 F. Supp. 2d at 497. This is particularly true given that the Insurer Plaintiffs do not identify

[98] Further, the fact that Celgene allegedly executed a covenant not to sue on the '217 Patent in actions against eight separate generic manufacturers (Humana Am. Compl. ¶ 299; *see also, e.g.*, MSP SAC ¶ 415), does not alone plausibly indicate that its suits asserting that patent were objectively baseless at the time they were filed. *See PRE*, 508 U.S. at 60 n.5.

which prior art rendered the '800 and '217 Patents invalid and do not explain how that prior art renders the '800 and '217 Patents anticipated and/or obvious. *Picone*, 2017 WL 4873506, at *7. As such, the Insurer Plaintiffs' allegations regarding the '800 and '217 Polymorph Patents are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.

The MSP Plaintiffs' Allegations. The MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically have expected to prevail on its infringement allegations as to its Polymorph Patents because: (i) Celgene's conduct in asserting the '357 Patent, the '598 Patent, and the '219 Patent was a sham and (ii) the '800 Patent and the '217 Patent were invalid as anticipated and/or obvious and were invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40). The Celgene Defendants argue that the MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity based on Celgene's conduct in asserting its Polymorph Patents. (Mov. Br. at 21–23). For the reasons set forth below, the Court agrees with the Celgene Defendants.

First, while the MSP Plaintiffs do not allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its Polymorph Patents because the '357 Patent, '598 Patent, and '219 Patent are invalid as anticipated or obvious, they do generally allege that Celgene's conduct in asserting these patents against its competitors was a sham because those patents were invalid and/or not infringed. (MSP SAC ¶¶ 367–81 & 399–469). Such conclusory legal allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. *Picone*, 2017 WL 4873506, at *6 (stating that in determining whether the plaintiffs have plausibly alleged the sham litigation exception to *Noerr-Pennington* immunity "the [c]ourt does not credit the purely conclusory legal allegations that the '290 Patent was 'objectively baseless' or that Shire engaged in 'sham patent litigation.'"); *Wellbutrin*, 868 F.3d at 149 ("[A]n

infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification."). Similarly, to the extent the MSP Plaintiffs generally allege that Celgene's conduct in asserting the '357 Patent, '598 Patent, and '219 Patent was objectively baseless, because those patents were weak, such generalized allegations are not sufficient to plausibly suggest that it was objectively baseless for Celgene to expect that the presumed validity of those patents could withstand a validity challenge. *See Picone*, 2017 WL 4873506, at *7; *Braintree Labs., Inc*, 568 F. Supp. 2d at 497.

Second, like the Insurer Plaintiffs, the MSP Plaintiffs also allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because, based on Celgene's successful arguments in a *Markman* proceeding, the '800 Patent and '217 Patent are invalid for failing to satisfy the definiteness, written description, and enablement requirements. (Opp. Br. at 40–41; MSP SAC ¶¶ 375–77 & 269–70). As already discussed above with respect to the Insurer Plaintiffs' allegations, the fact that Celgene may have faced a serious defense to any litigation asserting the '800 Patent or '217 Patent, regardless of the claim construction position it took with respect to the term hemihydrate appearing in those patents, is not sufficient to strip it of *Noerr-Pennington* immunity. *Novartis*, 902 F.3d at 15.

Third, the MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to the '800 and '217 Polymorph Patents because those patents were "obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent[s]" and are "obvious variants of the composition of matter patent, adding [a] further basis for invalidity."

(MSP SAC ¶ 270). As discussed with respect to the Insurer Plaintiffs' allegations, such conclusory allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.

In sum, in-so-far as the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act in part by bringing sham patent infringement lawsuits against various generic competitors to enforce its Polymorph Patents, as listed above, the Court finds that their allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. As such, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.[99]

d. The REMS Patents

The Insurer Plaintiffs' and MSP Plaintiffs' Allegations. The Insurer Plaintiffs and MSP Plaintiffs allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its REMS Patents because: (i) it fraudulently obtained certain REMS Patents and (ii) the prior art that led the PTAB to invalidate two of Celgene's REMS Patents (the '720 and '501 Patents), would invalidate other of Celgene's REMS Patents. (Opp. Br. at 37). The Celgene Defendants argue that the Insurer Plaintiffs and MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity based on Celgene's conduct in asserting its REMS Patents. (Mov. Br. at 23). Though the Celgene Defendants acknowledge that the PTAB invalidated two of Celgene's REMS Patents, they argue that whether a small subset of Celgene's patents have fared worse than others is insufficient as a matter of law to plead a sham

[99] In their Opposition Brief, the Insurer Plaintiffs and MSP Plaintiffs suggest that Celgene could not realistically expect to prevail in asserting any claims based on the Polymorph Patents because those patents were not infringed. (Opp. Br. at 40). Nevertheless, the Insurer Plaintiffs and MSP Plaintiffs did not provide any further explanation in their brief or at oral argument to explain why it was objectively baseless for Celgene to expect that its Polymorph Patents were infringed beyond those discussed. (*See generally* Opp. Br.). And the Insurer Plaintiffs and MSP Plaintiffs cannot plead the sham litigation exception to *Noerr-Pennington* immunity merely by alleging, in a conclusory fashion, that those patents were not infringed. *Wellbutrin*, 868 F.3d at 149; *Takeda*, 2021 WL 3144897, at *12.

litigation based on multiple patents. (*Id.*). They contend that where alleged sham litigation involves multiple patents, an antitrust plaintiff must allege that the litigation *as a whole* is objectively baseless. (*Id.*). And here, as the Celgene Defendants point out, the Insurer Plaintiffs and MSP Plaintiffs do not allege that any of the alleged sham lawsuits Celgene initiated against its competitors *only* involved the REMS Patents. Rather, they explain that those lawsuits involved multiple other types of patents as well. As such, the Celgene Defendants argue that the Insurer Plaintiffs and MSP Plaintiffs have failed to plead that Celgene's lawsuits asserting multiple types of patents against its competitors were objectively baseless as a whole. (*Id.*). In Opposition, the Insurer Plaintiffs and MSP Plaintiffs point out that the Honorable Katharine S. Hayden, U.S.D.J., has previously held that allegations as to a subset of patents may be sufficient to allege that an entire litigation is a sham. (Opp. Br. at 37 n.135). For the reasons set forth below, the Court agrees with the Celgene Defendants and follows binding Third Circuit precedent in finding that the Insurer Plaintiffs and MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity based on Celgene's conduct in asserting its REMS Patents.

In *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354 (3d Cir. 2016), the Third Circuit considered a challenge by the defendant to the District Court's ruling, under the *Noerr-Pennington* doctrine, that the defendant could not present evidence at trial of plaintiff's litigation conduct as a basis for the accusation of monopolistic conduct. *Avaya*, 838 F.3d at 413. More specifically, the defendant challenged the district court's determination that "the whole case has to be a sham" for the sham litigation exception to apply. *Id.* The defendant contended that this determination was made in error and that instead the sham exception should be applied on a claim-by-claim basis. *Id.* The Third Circuit rejected this argument, holding that "the whole case has to be a sham" for the sham exception to apply. *Id.* In so holding, the Third Circuit agreed with the District Court, which

explained that "cases often involve claims of varying degrees of merit, many of which are weeded out pre-trial, and it would be impractical to run a litigation system that made those kinds of claims subject to antitrust suits." *Id.* at 414. The Third Circuit further explained that while "one might imagine a situation where a single claim, separated from an otherwise arguably meritorious suit, is so harmful and costly to a defendant that it might impose anticompetitive harm on the defendant in a way that triggers the sham litigation exception to *Noerr–Pennington* . . . the Supreme Court's elaboration of the 'sham' exception suggests that we should not go hunting for that example." *Id.* The Third Circuit noted that while some of the plaintiff's "claims that were dismissed before trial may have been weak, [] they were part and parcel of a course of litigation that proceeded to two months of substantial evidence and argument to a jury." *Id.* As such, the court found that the plaintiff's litigation conduct was protected from antitrust liability by the *Noerr-Pennington* doctrine because the defendant could not show that the whole lawsuit was a sham. *Id.*

The Third Circuit employed similar reasoning in *Wellbutrin*. In *Wellbutrin*, the plaintiffs claimed that the defendant delayed the launch of generic versions of Wellbutrin, in part, by supporting the filing of a baseless citizen petition with the FDA, which expressed concerns regarding the sufficiency of the FDA's bioequivalence criteria for generic versions of Wellbutrin. *Wellbutrin*, 868 F.3d at 142, 154. In determining whether the citizen petition was entitled to *Noerr-Pennington* immunity, the district court considered the petition as a series of four requests and "concluded that two of the four requests were successful and thus not baseless, and that two of the four requests were potentially baseless." *Wellbutrin*, 868 F.3d at 156 n.34. Because the plaintiffs failed to show that their injury was attributable to the unsuccessful (and potentially sham) requests, rather than to the successful requests, the district court granted summary judgment in favor of the defendant. *Id.* The Third Circuit noted that it had "doubts about this reasoning" and explained

that the flaw in the district court's conclusion was in viewing the "[p]etition as four independent requests, rather than as a single petition." *Id.* The Third Circuit emphasized that "[w]hen considering whether a petition is entitled to immunity, courts should consider whether the petition *as a whole* is objectively baseless." *Id.* (emphasis added). As such, because "the District Court considered the merit of each of the [p]etition's constituent requests, [and] did not reach any conclusions regarding whether the [p]etition, in toto, was objectively baseless" the Third Circuit noted that the district court's "consideration of causation and delay was premature." *Id.* Together this Third Circuit precedent indicates that, in order to plausibly show that Celgene's lawsuits, which included the REMS Patents, were a sham, the Insurer Plaintiffs and MSP Plaintiffs must allege that those lawsuits asserting multiple other patents were objectively baseless *in toto*. This they have failed to do.

Here, neither the Insurer Plaintiffs nor the MSP Plaintiffs have alleged that any of the alleged sham lawsuits Celgene initiated against its competitors *only* involved the REMS Patents. (*See generally* Humana Am. Compl.; *see also* MSP SAC). In fact, the only lawsuits that the Insurer Plaintiffs and MSP Plaintiffs allege involved the REMS Patents include those Celgene filed against Natco, Alvogen, and Apotex. (Humana Am. Compl. ¶¶ 347–63, 388–98 & 446–69; MSP SAC ¶¶ 367–81, 428–37 & 462–69). The MSP Plaintiffs also allege that Celgene enforced its REMS Patents against Dr. Reddy's. (MSP SAC ¶¶ 382–98). However, all of those lawsuits also involved numerous other patents, including Celgene's '517 Compound Patent, Method of Treatment Patents, or Polymorph Patents. (Humana Am. Compl. ¶¶ 347–63 (alleging that Celgene asserted at least nine other patents in addition to REMS Patents against Natco), *id.* ¶¶ 388–98 (alleging that Celgene asserted at least fourteen other patents in addition to five REMS Patents against Alvogen) & *id.* ¶¶ 446–69 (alleging that Celgene asserted at least ten other patents in addition to five REMS

Patents against Apotex); *see also* MSP SAC ¶¶ 367–98, 428–37 & 462–69). As described above, the Insurer Plaintiffs and MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity as it relates to Celgene's conduct in asserting its non-REMS Patents in litigation, including its '517 Compound Patent, its Method of Treatment Patents, and its Polymorph Patents. The Court cannot plausibly infer that Celgene's *entire* lawsuits against Natco, Alvogen, Apotex, and Dr. Reddy's amounted to a sham based solely on Celgene's decision to include certain of the REMS Patents in those suits when those lawsuits involved multiple other patents for which Celgene did plausibly have a realistic expectation of success on the merits.

As the Third Circuit noted in *Avaya*, "cases often involve claims of varying degrees of merit, many of which are weeded out pre-trial, and it would be impractical to run a litigation system that made those kinds of claims subject to antitrust suits." *Avaya*, 838 F.3d at 414. To be sure, "one might imagine a situation where a single claim, separated from an otherwise arguably meritorious suit, is so harmful and costly to a defendant that it might impose anticompetitive harm on the defendant in a way that triggers the sham litigation exception to *Noerr–Pennington*." *Id.* However, the Third Circuit emphasized that "the Supreme Court's elaboration of the 'sham' exception suggests that [courts] should not go hunting for that example." *Id.* And this case does not provide such an example. More specifically, neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that Celgene's conduct in asserting its REMS Patents somehow dominated the lawsuits it filed against Natco, Alvogen, Apotex, or Dr. Reddy's. In fact, their allegations show just the opposite. The Insurer Plaintiffs allege that, after Celgene's '720 Patent was invalidated by the PTAB, Celgene agreed to stay all proceedings related to its REMS Patents pending the Federal Circuit's review of the PTAB's decision. (Humana Am. Compl. ¶¶ 395 & 454; *see also* MSP SAC ¶ 466). They further allege that after the Federal Circuit affirmed the PTAB decision Celgene

stopped pressing its REMS Patents in litigation against generics. (Humana Am. Compl. ¶ 302; *see also* MSP SAC ¶ 466). As such, the Court cannot plausibly infer that Celgene's *entire* lawsuits against Natco, Alvogen, Apotex, and Dr. Reddy's amounted to a sham based solely on Celgene's decision to include certain of the REMS Patents in those suits when those lawsuits involved multiple other patents for which Celgene did plausibly have a realistic expectation of success on the merits. *See Avaya*, 838 F.3d at 413–14; *Wellbutrin*, 868 F.3d at 156 n.34. Because the Insurer Plaintiffs and MSP Plaintiffs have failed to plausibly allege that the lawsuits in which Celgene asserted its REMS Patents against its competitors were objectively baseless *in toto*, the Court finds that the Insurer Plaintiffs and MSP Plaintiffs have failed to plead the sham litigation exception to *Noerr-Pennington* immunity. *See, e.g., Trs. of Univ. of Pa. v. St. Jude Children's Rsch. Hosp.*, 940 F. Supp. 2d 233, 241, 247 (E.D. Pa. 2013) ("St. Jude's request for injunctive relief was part of the lawsuit, so the University's argument—that the allegedly 'baseless and unfounded demand' is a separate activity not protected under *Noerr-Pennington*—does not persuade."); *Meridian Project Sys., Inc. v. Hardin Const. Co.*, 404 F. Supp. 2d 1214, 1221–22 (E.D. Cal. 2005) (finding allegation that a single claim was objectively baseless insufficient to bring filing of entire complaint which contained seven other claims within the sham exception on motion to dismiss because "to fall within the sham exception, Meridian's filing of the *lawsuit* must be objectively baseless"); *Humira*, 465 F. Supp. 3d at 834 ("Some of AbbVie's conduct was not immunized by the *Noerr-Pennington* doctrine—including what plaintiffs allege to be the heart of their monopolization claim—but much of what preceded and followed that conduct was immunized, which makes the entirety of alleged monopolization scheme immune.").

In sum, in-so-far as the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act in part by bringing sham patent infringement lawsuits against generic

competitors to enforce its REMS Patents the Court finds that their allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. As such, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

e. The Orange Book

The Insurer Plaintiffs and MSP Plaintiffs next allege that no reasonable litigant in Celgene's shoes could realistically expect to prevail on its infringement allegations as to its '357, '598 and '219 Polymorph Patents because those patents were not listed in the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. (Opp. Br. at 28 n.96; Humana Am. Compl. ¶ 390, 400, 403 & 412; MSP SAC ¶ 434). More specifically, they allege that Celgene was required to list with its NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). The Insurer Plaintiffs and MSP Plaintiffs allege that by asserting these patents that were not listed in the Orange Book, "Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly, which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend its monopoly." (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). However, the Celgene Defendants contend that patents that do not cover a brand product need not be listed in the Orange Book, even if the patents cover a generic product. (Mov. Br. at 22–23). They point out that the Insurer Plaintiffs and MSP Plaintiffs acknowledge that at least one generic manufacturer agreed that its product infringed Celgene's unlisted Polymorph Patents. (*Id.* at 23). As such, they argue that the fact that Celgene asserted certain of its Polymorph Patents against

generic competitors that were not listed in the Orange Book is irrelevant to Plaintiffs' sham litigation claims. (*Id.*). For the reasons set forth below, the Court agrees with the Celgene Defendants.

21 U.S.C. § 355(b)(1) calls for a patent to be listed in the Orange Book if it "claims the drug for which the applicant submitted the [NDA] application" or "claims a method of using such drug." 21 U.S.C. § 355(b)(1); *see also Astellas US LLC v. Hospira, Inc.*, No. 18-1675, 2022 WL 1591277, at *2 (D. Del. May 19, 2022), *aff'd,* No. 2022-1878, 2022 WL 17998229 (Fed. Cir. Dec. 30, 2022); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 18-3632, 2018 WL 5263278, at *1 (D.N.J. Oct. 23, 2018). Here, the Insurer Plaintiffs and MSP Plaintiffs do not allege that the '357, '219, and '598 Polymorph Patents contain any method of use claims. As such, under 21 U.S.C. § 355(b)(1), Celgene was required to list these Polymorph Patents in the Orange Book if they claimed the drug for which the applicant submitted the NDA. In *Apotex, Inc. v. Thompson*, the Federal Circuit explained that to "claim[ ] the drug for which the NDA was submitted" means that "a patent must be listed if it contains a product claim that reads on the drug that is the subject of the NDA. . . ." 347 F.3d 1335, 1343–44 (Fed. Cir. 2003) (emphasis added); *see also United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 132 (2d Cir. 2021); *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020); (*see also* Tr. of Sept. 8, 2023 Oral Arg. at 205:15–19). As the Celgene Defendants pointed out at oral argument (Tr. of Sept. 8, 2023 Oral Arg. at 208:15–21), neither the Insurer Plaintiffs nor the MSP Plaintiffs allege that the '357, '219, and '598 Polymorph Patents contain product claims that read on the drug that is the subject of Celgene's NDA—*i.e.*, Revlimid. (Humana Am. Compl. ¶ 390; MSP SAC ¶ 434). Rather, they merely allege that Celgene believed those Polymorph Patents were infringed by generic manufacturers seeking to bring generic

alternatives to Revlimid or *lenalidomide* to market. (Humana Am. Compl. ¶¶ 390, 400, 412, 295 & 355 (explaining that '357, '219 and '598 Polymorph Patents claim embodiments of lenalidomide, specifically); MSP SAC ¶ 434).[100] Accordingly, because the Insurer Plaintiffs and MSP Plaintiffs do not allege that the '357, '219, and '598 Polymorph Patents claim Revlimid, specifically, the Court cannot infer that Celgene engaged in procedural misconduct by failing to list those patents in the Orange Book. Nor can the Court infer that Celgene's lawsuits asserting those Polymorph Patents were a sham because those patents were not listed in the Orange Book. As such, that component of the overall scheme, on its own, cannot support a claim under Section 2 of the Sherman Act.

In sum, in-so-far as the Insurer Plaintiffs and MSP Plaintiffs allege that Celgene violated Section 2 of the Sherman Act in part by bringing sham patent infringement lawsuits against various generic competitors to enforce its patents the Court finds that their allegations are insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity.[101] As such, that component of the overall scheme cannot on its own support a claim under Section 2 of the Sherman Act.

vi. The Co-Pay Assistance Allegations

The MSP Plaintiffs, specifically, contend that the Celgene Defendants violated Section 2 of the Sherman Act in part by executing a co-payment circumvention scheme with CDF and PAN to

[100] Revlimid is Celgene's branded version of lenalidomide. Lenalidomide is simply the active ingredient in that product. (Humana Am. Compl. ¶¶ 4 & 39; MSP SAC ¶¶ 6, 52 & 265; Tr. of Sept. 8, 2023 Oral Arg. at 206:15–23).

[101] To the extent that the Insurer Plaintiffs or MSP Plaintiffs allege that Celgene's conduct in asserting any other patents in addition to its '517 Patent, Method of Treatment Patents discussed above, Polymorph Patents, and REMS Patents, was objectively baseless, the Court finds that any such allegations are conclusory and insufficient to plead the sham litigation exception to *Noerr-Pennington* immunity. (*See generally* Humana Am. Compl. ¶¶ 347–539; MSP SAC ¶¶ 367–469). The Insurer Plaintiffs and MSP Plaintiffs cannot plead the sham litigation exception to *Noerr-Pennington* immunity merely by alleging, in a conclusory fashion, that Celgene's patents were invalid and/or not infringed. *Picone*, 2017 WL 4873506, at *6–7; *Wellbutrin*, 868 F.3d at 149. Regardless, the Insurer Plaintiffs and MSP Plaintiffs have wholly failed to explain, both in their Opposition Brief and at oral argument, how Celgene's conduct in asserting any patents in addition to its '517 Patent, Method of Treatment Patents discussed above, Polymorph Patents, and REMS Patents on the bases discussed above was objectively baseless. (*See generally* Opp. Br.; Tr. of Sept. 8, 2023 Oral Arg.).

fund patient copays of its Thalomid and Revlimid drugs, which caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and in turn caused the MSP Plaintiffs' Assignors to overpay for those drugs. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 244 ("MSP Supp. Opp.")). According to the MSP Plaintiffs, Celgene realized it could overcome doctor and patient cost concerns regarding Thalomid and Revlimid by secretly subsidizing patient co-pay obligations for its drugs through PAN and CDF. (MSP SAC ¶ 510). More specifically, the MSP Plaintiffs explain that it is well recognized that an insured's co-pay sharing obligations serve as a market-based check on drug pricing. (*Id.* ¶ 515). By surreptitiously underwriting these cost-sharing obligations, Celgene allegedly created the illusion for physicians and patients that Revlimid and Thalomid were "free" when Celgene had merely shifted the entire price burden to third-party payors. (*Id.*). The MSP Plaintiffs allege that, as a result of this scheme, Celgene was able to artificially inflate its prices for Revlimid and Thalomid because it effectively removed the "remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price." (*Id.* ¶ 514). The MSP Plaintiffs contend that this co-pay scheme violated Section 2 of the Sherman Act. (*See generally* MSP Supp. Opp.)

In moving to dismiss the MSP Plaintiffs' Second Amended Complaint, the Celgene Defendants did not address whether the MSP Plaintiffs' co-pay allegations could support a claim under Section 2 of the Sherman Act. (*See generally* Mov. Br. & Reply). Nevertheless, at oral argument, the MSP Plaintiffs insisted that their co-pay allegations support all counts of their Second Amended Complaint, including Count I, which alleges a violation of Section 2 of the Sherman Act. (MSP SAC ¶¶ 575–82; Tr. of Sept. 8, 2023 Oral Arg. at 224:8–19). When asked why they did not move to dismiss the MSP Plaintiffs' co-pay allegations insofar as they were being

brought under Count I, the Celgene Defendants stated that they did not understand the co-pay allegations to have been brought under the antitrust counts. (Tr. of Sept. 8, 2023 Oral Arg. at 225:5–13). In other words, the Celgene Defendants contended that the MSP Plaintiffs' Second Amended Complaint did not provide them with sufficient notice that the co-pay allegations were brought under Count I, which alleges a violation of Section 2 of the Sherman Act. (*Id.* at 226:18–20). After oral argument, on September 26, 2023, the Court ordered supplemental briefing regarding why the Celgene Defendants were not on sufficient notice that the co-pay allegations in the MSP Plaintiffs' Second Amended Complaint were being brought under Count I. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 235)). The parties have since submitted supplemental briefing on this issue. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 240 ("Celgene Supp. Br."); MSP Supp. Opp. & D.E. No. 246 ("Celgene Supp. Reply"))).

In their supplemental brief, the Celgene Defendants maintain that the MSP Plaintiffs' factual allegations did not inform them that the MSP Plaintiffs viewed their co-pay allegations as part of a monopolistic scheme that violated Section 2 of the Sherman Act. First, Celgene points out that the hundreds of paragraphs in the MSP Plaintiffs' Second Amended Complaint maintain a rigid distinction "between allegations of *anticompetitive conduct* through which Celgene allegedly unlawfully kept generic competition off the market" in violation of the antitrust laws, and "allegations of a *charitable co-pay assistance scheme* that *independently* enabled Celgene to charge more for its products," in violation of RICO as well as consumer protection laws. (Celgene Supp. Br. at 3–4). They maintain that Count I, which alleges violations of Section 2 of the Sherman Act, refers to Celgene's alleged efforts to delay and block entry of generic products and makes no reference to co-pay donations or how co-pay donations delay and block entry of generic products.

(*Id.* at 5). Second, the Celgene Defendants maintain that the MSP Plaintiffs' factual allegations did not inform Celgene that the MSP Plaintiffs viewed their co-pay allegations as part of a monopolistic scheme that violated Section 2 of the Sherman Act because the MSP Plaintiffs' co-pay assistance allegations have nothing to do with competition. (*Id.* at 2–3). Third, the Celgene Defendants note that despite the fact that they argued in their moving brief that the MSP Plaintiffs stated "no claims for anticompetitive conduct," the MSP Plaintiffs failed to explain why their Section 2 claim under Count I should proceed based on the co-pay allegations. (*Id.* at 6–8). As such, the Celgene Defendants contend that, insofar as the co-pay allegations are being brought under Section 2 of the Sherman Act, any such theory has been abandoned. (*Id.* at 7–8).

In their supplemental opposition, the MSP Plaintiffs maintain that it was clear on the face of their Second Amended Complaint that the co-pay allegations were being brought under all counts, including Count I, and as such Celgene has waived any argument that those allegations are insufficient to support a Section 2 violation. First, they contend that the Second Amended Complaint contains allegations describing the co-pay circumvention scheme as part of an illegal, multi-prong anticompetitive scheme to eliminate price sensitivity to Thalomid and Revlimid. (MSP Supp. Opp. at 5–7). Second, because Count I incorporated and adopted all of the factual allegations in the Second Amended Complaint, the MSP Plaintiffs maintain that it was clear that the co-pay allegations were being brought under all counts. (*Id.* at 7). Third, the MSP Plaintiffs contend that statements in discovery hearings and discovery rulings made by the Honorable Michael A. Hammer, U.S.M.J., alerted Celgene as to the scope of their co-pay allegations. (*Id.* at 8). Based on these submissions, the Court must consider whether the MSP Plaintiffs' Second Amended Complaint provided the Celgene Defendants with sufficient notice that their co-pay allegations support its antitrust claim under Section 2 of the Sherman Act. For the reasons set

forth below, the Court finds that the Second Amended Complaint has failed to provide the Celgene Defendants with such notice.

Rule 8(a)(2) requires that a pleading include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although Rule 8(a)(2) does not require a pleading to state the elements of a prima facie case, it does require the pleading to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 346 (2005). The purpose of this rule is to "facilitate a proper decision on the merits." *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002). A complaint that fails to comply with this rule "presents far too a heavy burden in terms of defendants' duty to shape a comprehensive defense and provides no meaningful basis for the Court to assess the sufficiency of [plaintiff's] claims." *Gonzales v. Wing*, 167 F.R.D. 352, 355 (N.D.N.Y. 1996), *aff'd*, 113 F.3d 1229 (2d Cir. 1997). "A district court may sua sponte dismiss a complaint for failure to comply with Rule 8." *Tucker v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 645 F. App'x 136, 137 (3d Cir. 2016). Further, a district court is empowered to dismiss a complaint *sua sponte* under Rule 12(b)(6), even as to non-moving defendants, as long as the plaintiff has notice and an opportunity to respond. *See, e.g.*, *Oatess v. Sobolevitch*, 914 F.2d 428, 430 n.5 (3d Cir. 1990) (approving, in at least some cases, *sua sponte* dismissal after service of process when plaintiff is given the opportunity to respond); *Briscoe v. Klaus*, 538 F.3d 252, 259 (3d Cir. 2008) (approving *sua sponte* dismissal when district court has "acquired knowledge of the facts it needs to make an informed decision.").

Here, the Court finds that the MSP Plaintiffs' factual allegations did not put the Celgene Defendants on sufficient notice that their co-pay allegations were being brought under Count I, which alleges a violation of Section 2 of the Sherman Act. To start, as the Celgene Defendants

point out, the MSP Plaintiffs' Second Amended Complaint maintains a distinction between allegations of anticompetitive conduct on the one hand, through which Celgene allegedly kept generic competitors off the market (MSP SAC ¶¶ 40–501), and allegations of a co-pay circumvention scheme on the other hand, that independently enabled Celgene to artificially inflate its prices for Revlimid and Thalomid. (MSP SAC ¶¶ 502–52; Celgene Supp. Br. at 3–4). More specifically, after introducing their Second Amended Complaint and describing the economic and regulatory background relevant to their allegations, in Section VI the MSP Plaintiffs outline allegations of Celgene's anticompetitive conduct. Section VI describes how Celgene anticompetitively delayed and stunted generic competition through a scheme that consisted of, e.g., (i) citing the REMS safety programs as a pretext for refusing to sell generics samples; (ii) paying off the first-to-file, would-be generic competitor through a secret, "pay-for-delay" settlement agreement and reinforcing the first-to-file payoff through later settlements with later would-be generics; (iii) obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; and (iv) prosecuting many patent litigations where Celgene had no realistic likelihood of prevailing on the merits. (MSP SAC ¶¶ 106–469). Notably absent from this portion of the MSP Plaintiffs' Second Amended Complaint, which outlines Celgene's anticompetitive conduct, are any allegations that concern the co-pay circumvention scheme. (*See id.*). Next, the MSP Plaintiffs describe how Celgene (i) intended to and did harm competition (Section VII), (ii) foreclosed generic competition (Section VIII and IX), (iii) maintained monopoly power (Section X), (iv) monopolized the relevant market (Section XI), and (v) caused antitrust injury (Section XII). (*Id.* ¶¶ 470–501). Again, wholly absent from these portions of the MSP Plaintiffs' Second Amended Complaint are any allegations that concern the co-pay circumvention scheme. (*See id.*). It is only after laying out five hundred paragraphs on Celgene's alleged

anticompetitive conduct and unlawful monopolization that the MSP Plaintiffs then set forth allegations of a co-pay circumvention scheme through which Celgene was able to artificially inflate its prices for Revlimid and Thalomid. (*Id.* ¶¶ 502–52). Wholly absent from this portion of the MSP Plaintiffs' Second Amended Complaint are any allegations describing how the co-pay circumvention scheme harmed competition and delayed generic entry in the markets for Revlimid and Thalomid. (*See id.*).

Further, as the Celgene Defendants point out, Count I, which alleges violations of Section 2 of the Sherman Act, makes no reference to the co-pay circumvention scheme allegations. (*Id.* ¶¶ 575–82). In fact, in Count I, the MSP Plaintiffs only allege that the Celgene Defendants violated Section 2 of the Sherman Act by engaging in an "anticompetitive scheme to delay and block entry of AB-rated generic equivalents of Thalomid and Revlimid." (*Id.* ¶ 576). Yet, as the Celgene Defendants point out (Celgene Supp. Br. at 2–3), nowhere in their Second Amended Complaint do the MSP Plaintiffs allege how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid"—which is central to the MSP Plaintiffs' Section 2 claim. (MSP SAC ¶ 576). Rather, the MSP Plaintiffs allege that Celgene's co-pay circumvention scheme created the illusion for physicians and patients that Revlimid and Thalomid were "free" when Celgene had merely shifted the entire price burden to third-party payers, allowing Celgene to artificially inflate its prices for Revlimid and Thalomid. (*Id.* ¶¶ 514–15). In other words, as the Celgene Defendants point out (Celgene Supp. Br. at 3), the MSP Plaintiffs' co-pay allegations relate to price shifting and increasing prices. However, allegations that co-pay contributions eliminated price sensitivity and increased prices say nothing about how those contributions delayed and blocked generic competition. Accordingly, because the MSP Plaintiffs' Second Amended Complaint (i) maintains a distinction between allegations of

anticompetitive conduct on the one hand, through which Celgene allegedly kept generic competitors off the market (MSP SAC ¶¶ 40–501), and allegations of a co-pay circumvention scheme on the other hand, through which Celgene was independently able to eliminate price sensitivity to Thalomid and Revlimid and artificially inflate its prices for those drugs (MSP SAC ¶¶ 502–52); (ii) wholly fails to mention the co-pay circumvention scheme in Count I; and (iii) contains no allegations regarding how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid," the Court finds that the MSP Plaintiffs' factual allegations did not put the Celgene Defendants on sufficient notice that the co-pay allegations were being brought under Count I.

In addition, as the Celgene Defendants point out (Celgene Supp. Br. at 6–8; Celgene Supp. Reply at 1), although they in their motion to dismiss repeatedly requested that the Court dismiss *all* Counts of the MSP Plaintiffs' Second Amended Complaint, the MSP Plaintiffs at no point in their opposition raised any arguments as to why their Section 2 claim should nevertheless proceed based on the co-pay allegations. (*See, e.g.*, Mov. Br. at 2 ("The Court should dismiss all counts."); *id.* at 5 ("The Court should dismiss all counts with prejudice."); *id.* at 11 ("Plaintiffs state no claims for anticompetitive conduct"); *see generally* Opp. Br.). In fact, when describing the actions that Celgene took to delay and stunt generic competition in violation of the antitrust laws in their Opposition Brief, the MSP Plaintiffs make no mention of the co-pay allegations whatsoever. (Opp. Br. at 13–14 ("The purchasers plausibly allege that Celgene and, later BMS delayed and stunted generic competition, *e.g.*, (1) by citing the REMS safety programs as a pretext for refusing to sell generics samples; (2) by obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; (3) by prosecuting over a dozen patent litigations where they had no realistic likelihood of prevailing on the merits; (4) by eventually paying off the first-to-file, would-

be generic competitor through secret, "pay-for-delay" settlement agreement; and (5) by reinforcing the first-to-file payoff through later settlements with later would-be generics."). This further indicates that the Celgene Defendants were not on notice that the co-pay circumvention scheme was part of a multi-prong anticompetitive scheme to monopolize the markets for Thalomid and Revlimid.[102] *Maugain v. FCA US LLC*, No. 22-0116, 2023 WL 179611, at *12 (D. Del. Feb. 7, 2023) ("The [c]ourt relies on [p]laintiffs to identify the allegations that support their claims.")

The MSP Plaintiffs' arguments to the contrary are unavailing. *First*, the MSP Plaintiffs contend that the Second Amended Complaint contains allegations that the co-pay circumvention scheme was part of an illegal, multi-prong anticompetitive scheme. (MSP Supp. Opp. at 5–7). To support this argument, the MSP Plaintiffs cite to a few paragraphs in their Second Amended Complaint that they argue plainly put the Celgene Defendants on notice that the co-pay allegations were being brought under all counts, including Count I, which alleges a violation of Section 2 of the Sherman Act. (Tr. of Sept. 8, 2023 Oral Arg. at 231:3–7 & 240:4–11 (citing MSP SAC ¶¶ 1–8, 122–135, 502, 510, & 513); MSP Supp. Opp. at 3–7 (citing MSP SAC ¶¶ 1, 7, 502, 506, 510, 513–15, 576, 629, 633, & 648)). To start, the MSP Plaintiffs point to paragraph 1 of their Second Amended Complaint, which provides: "Plaintiffs bring this action for violations of federal and state statutes, arising out of Defendants' involvement in *anticompetitive schemes*, that (1) prevented generic brands from entering the market to compete with Celgene's high-priced drugs Thalomid and Revlimid, *and* (2) provided illegal kickbacks that reduced market sensitivity to price increases, thus increasing prescription volume by secretly subsidizing patient co-payment, co-

[102] The Celgene Defendants argue that the MSP Plaintiffs' failure to raise any arguments in their Opposition Brief as to why their Section 2 claim should proceed based on their co-pay allegations is not merely a notice problem but an abandonment problem. (Celgene Supp. Br. at 8). Nevertheless, as will be set forth below, although the MSP Plaintiffs' Second Amended Complaint did not afford the Celgene Defendants with sufficient notice that the co-pay circumvention scheme was part of an illegal, multi-prong anticompetitive scheme to monopolize the markets for Thalomid and Revlimid, the Court will grant the MSP Plaintiffs one final opportunity to amend their allegations to support their Section 2 claim.

insurance, or deductible (collectively, "co-pay") obligations for its drugs through 501(c)(3) charities." (MSP SAC ¶ 1 (emphasis added)). Likewise, they cite to paragraph 7, which provides: "Unsatisfied with the profit realized from these products, Celgene chose to engage in an illegal, multi-prong, anticompetitive scheme. First, Celgene unlawfully maintained market exclusivity for these drugs by interfering with competitors' efforts to develop or obtain FDA approval for generic versions of Thalomid and Revlimid. *Second*, Celgene illegally funneled money through co-payment charities to subsidize the co-payments of Medicare beneficiaries, in violation of the federal anti-kickback statute, thus eliminating a major factor in price sensitivity for these patients." (*Id.* ¶ 7 (emphasis added)). Further, they point to the title of Section XIII of their Second Amended Complaint, which states that "Celgene Employ[ed] 501(c)(3)s as a Conduit to Commit Additional RICO *and* Antitrust Injuries" and paragraph 502, which states that "[t]he agreements between Celgene and CDF and Celgene and PAN[] *harmed competition* in the markets for Revlimid and Thalomid and other oncology drugs." (*Id.* at 122 & ¶ 502 (emphasis added); *see also id.* ¶ 506 ("Having worked to exclude generics from the market under the conduct described above and secure for itself a monopoly in the markets for Revlimid and Thalomid, Celgene consistently raised the price of Revlimid and Thalomid year-over-year"). Based on these sporadic and conclusory allegations, the MSP Plaintiffs contend that the Second Amended Complaint provided the Celgene Defendants with notice that the co-pay scheme was a necessary element to Celgene's anti-competitive conduct.

The Court disagrees. The fact that the MSP Plaintiffs allege in a conclusory fashion—in a few sentences of a 176 page Second Amended Complaint—that the co-pay assistance allegations were part of an illegal, multi-prong, anticompetitive scheme that harmed competition is not sufficient, in the Court's view, to have placed the Celgene Defendants on notice that the MSP

Plaintiffs' co-pay allegations were being asserted under Count I, which alleges a violation of Section 2 of the Sherman Act. As the Celgene Defendants point out (Celgene Supp. Reply at 2–3), the MSP Plaintiffs' allegations that the co-pay assistance arrangements were part of "an illegal, multi-prong, anticompetitive scheme" that "harmed competition" are conclusions, rather than allegations of fact. (*See* MSP SAC ¶¶ 1, 7, 502 & 506; *id.* at 122). Further, even though the MSP Plaintiffs sporadically allege that the co-pay arrangements harmed competition, they at no point allege how that scheme harmed competition. More specifically, as recounted above, the Second Amended Complaint contains no allegations regarding how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid"—which is central to the MSP Plaintiffs' Section 2 claim.[103] (*Id.* ¶ 576). As such, the Court finds that the MSP Plaintiffs' sporadic references to competition in connection with the co-pay scheme is not sufficient to have placed the Celgene Defendants on notice that the co-pay allegations were being brought under Count I.[104]

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[103] In its supplemental brief, the Celgene Defendants argue that the "first and most obvious" problem with MSP's contention that the co-pay allegations are part of an "overall anticompetitive scheme" is that their allegations say nothing about how those contributions harmed competition. (Celgene Supp. Br. at 2–3). In opposition, the MSP Plaintiffs argue that the Court should disregard such arguments because it is a merits argument rather than an explanation of why the Celgene Defendants were not on notice of such a theory. (MSP Supp. Opp. at 4). However, as the Celgene Defendants point out, the fact that the MSP Plaintiffs' Second Amended Complaint says nothing about how the co-pay arrangements delayed and blocked entry of AB-rated generic equivalents of Thalomid and Revlimid supports why the Celgene Defendants cannot have been on notice of any such theory. (Celgene Supp. Reply at 2).

Regardless, to state a plausible claim for relief under Section 2 of the Sherman Act, a plaintiff must show that the defendant (i) possessed "monopoly power in the relevant market" and (ii) willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Broadcom*, 501 F.3d at 307. Here, as described above, the MSP Plaintiffs' Second Amended Complaint plainly does not contain sufficient allegations to satisfy the second element, also known as the requirement of "anticompetitive" or "exclusionary" conduct, as to their co-pay allegations because the Second Amended Complaint contains no allegations regarding how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid." The MSP Plaintiffs' conclusory allegations—in only a few sentences of a 176 page Second Amended Complaint—that the co-pay assistance arrangements were part of "an illegal, multi-prong, anticompetitive scheme" that "harmed competition," does not alter the Court's conclusion given that those allegations are conclusions, rather than allegations of fact. As such, to the extent the MSP Plaintiffs purport to assert their co-pay allegations under Count I, such allegations are plainly insufficient.

[104] To support their argument that the Second Amended Complaint contains allegations indicating that the co-pay circumvention scheme supports their antitrust counts, the MSP Plaintiffs also cite to paragraphs 2–6, 8, 122–35,

Second, because Count I expressly incorporated and adopted all of the factual allegations in the Second Amended Complaint, the MSP Plaintiffs maintain that it was clear that the co-pay allegations were being brought under Count I. (MSP Supp. Opp. at 7). Again, the Court disagrees. A pleading containing an incorporation by reference must still meet the requirements of Federal Rule of Civil Procedure 8(a)(2), including that it contain a "short and plain statement of the claim showing the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This means that the adoption "must provide a degree of clarity which enables the responding party to ascertain the nature and extent of the incorporation." *Arunachalam v. Pazuniak*, No. 15-0259, 2018 WL 4603265, at *3 (D. Del. Sept. 25, 2018) (internal quotation marks and citation omitted). In fact, the Third Circuit has an established policy against shotgun pleadings, which include complaints containing multiple counts where each count adopts the allegations of all preceding counts. *See Fuhrman v. Mawyer*, No. 21-2024, 2023 WL 5672314, at *4 (M.D. Pa. Sept. 1, 2023) (citing *Hynson ex rel. Hynson v. City of Chester Legal Dep't*, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988)). Here, the Court finds that the incorporation by reference fails to sufficiently clarify that the co-pay allegations support Count I, particularly since, as described above, the MSP Plaintiffs' Second Amended Complaint (i) maintains a distinction between allegations of anticompetitive conduct on the one hand (MSP SAC ¶¶ 40–501) and allegations of a co-pay circumvention scheme on the other hand (*id.* ¶¶ 502–52); (ii) wholly fails to mention the co-pay circumvention scheme in Count I, which alleges violations

510, 513–515, 576, 629, 633, and 648. (Tr. of Sept. 8, 2023 Oral Arg. at 231:3–7 & 240:4–11; *see* MSP Supp. Opp. at 3). None of those allegations, however, describe how the co-pay assistance arrangements were part of "an illegal, multi-prong, anticompetitive scheme" that "harmed competition." (*See* MSP SAC ¶¶ 2–6 (providing background on Celgene's development of Thalomid and Revlimid and investigations into Celgene's high pricing of the drugs); *id.* ¶ 8 (detailing Celgene's anticompetitive scheme but not mentioning co-pay arrangements); *id.* ¶¶ 122–35 (describing how Celgene cited the REMS safety programs as a pretext for refusing to sell generics samples and not mentioning the co-pay circumvention scheme); *id.* ¶¶ 510 & 513–15 (describing how Celgene was able to artificially inflate its prices for Revlimid and Thalomid because it effectively removed the remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price.); *id.* ¶¶ 576, 629, 633 & 648 (referencing antitrust counts and claim for unjust enrichment which do not reference co-pay allegations)).

of Section 2 of the Sherman Act; and (iii) contains no allegations regarding how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid." (*Id.* ¶ 576). This is further bolstered by the fact that, to support their RICO counts, the MSP Plaintiffs likewise incorporate by reference the entirety of their Second Amended Complaint. (*See, e.g.*, *id.* ¶¶ 583 & 614). Yet, the MSP Plaintiffs do not purport to contend that Celgene's other conduct, e.g., (i) citing the REMS safety programs as a pretext for refusing to sell generics samples; (ii) paying off the first-to-file, would-be generic competitor through a secret, "pay-for-delay" settlement agreement and reinforcing the first-to-file payoff through later settlements with later would-be generics (iii) obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; and (iv) prosecuting over a dozen patent litigations where they had no realistic likelihood of prevailing on the merits, violated the RICO statutes. (*Id.* ¶¶ 106–469). Accordingly, the mere fact that Count I incorporated and adopted all of the factual allegations in the Second Amended Complaint by reference is not sufficient to have placed the Celgene Defendants on notice that the MSP Plaintiffs' co-pay allegations were being asserted under Count I.

Third, the MSP Plaintiffs contend that statements in discovery hearings and discovery rulings made by Judge Hammer alerted the Celgene Defendants as to the proper scope of their co-pay allegations. (MSP Supp. Opp. at 2–3 & 8). To start, the MSP Plaintiffs contend that the Celgene Defendants were on notice that the MSP Plaintiffs' co-pay allegations were being asserted under Count I based on discussions of the scope of their allegations during an August 29, 2022 telephonic status conference with Judge Hammer. (*Id.* at 1–2). More specifically, they point out that during the conference, the following exchange occurred:

> THE COURT: . . . In other words, the copays that plaintiffs say were intended to create market price stability and discourage medically

> unnecessary treatment. Because Celgene made donations that really were designed to let the Medicare recipients not have to pay the copay for Thalidomide and Revlimid. And as a result of that MSP had to pay for prescriptions for Thalidomide and Revlimid that could have been filled by less expensive generic formulations; right?
>
> MR. DAVIS: That's right Your Honor but the—I guess to make sure I'm conveying my point. My point is that the—the use of the 501(c) entities, the defendants here are really a conduit of Celgene's you know misconduct that we're alleging in the action, right the filing of sham litigation, is using a 501(c) as a conduit to stifle competition. So it's part and parcel of the misconduct we're alleging against the main defendants, but they're working with them to manipulate the market, stifle competition and exercise, you know, monopolistic power unlawfully.

(D.E. No. 113 at 33:19–34:13). According to the MSP Plaintiffs, this colloquy plainly put the Celgene Defendants on notice that the MSP Plaintiffs' co-pay allegations were being asserted under Count I. In fact, they assert that despite being present on the call, the Celgene Defendants did not contest the above characterization of the MSP Plaintiffs' allegations. (MSP Supp. Opp. at 2). The Court is not convinced that this cursory discussion at the August 29, 2022 status conference sufficiently put the Celgene Defendants on notice that the MSP Plaintiffs' co-pay allegations were being asserted under Count I. As an initial matter, as the Celgene Defendants point out (Celgene Supp. Reply at 6), the August 29, 2022 status conference took place *after* the Celgene Defendants had already served their motion to dismiss on the MSP Plaintiffs on August 26, 2022. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 108)).[105] As stated above, although the Celgene Defendants in their motion to

[105] While the MSP Plaintiffs contend that the Celgene Defendants filed their motion to dismiss two and a half months after the August 29, 2022 status conference, that statement is misleading. (MSP Supp. Opp. at 2). In a teleconference held on March 7, 2022, the Court directed the parties to use this District's former Appendix N procedure in connection with the Celgene Defendants' consolidated motion to dismiss. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 31 & 39)). According to that procedure, the Celgene Defendants were directed to serve their motion to dismiss papers on the MSP Plaintiffs on August 26, 2022 and then file all motion papers simultaneously on the docket on November 15, 2022. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 85)). The Celgene Defendants did in

dismiss repeatedly requested that the Court dismiss *all* Counts of the MSP Plaintiffs' Second Amended Complaint, the MSP Plaintiffs at no point in their opposition raised any arguments as to why their Section 2 claim should nevertheless proceed based on their co-pay allegations. (*See, e.g.*, Mov. Br. at 2, 5 & 11; *see generally* Opp. Br.). As such, a statement made at a status conference on August 29, 2022, could not have provided the Celgene Defendants with notice before they briefed their motion to dismiss that the MSP Plaintiffs' co-pay allegations were being asserted under Count I. Regardless, the MSP Plaintiffs' characterization of their allegations at a status conference—bereft of any citations to where such characterizations appear in their Second Amended Complaint—does not indicate that their Second Amended Complaint put the Celgene Defendants on notice that the co-pay arrangements were allegedly part of Celgene's anticompetitive scheme to exclude generic competition in the markets for Thalomid and Revlimid. For the reasons already described above, the Court finds that their Second Amended Complaint failed to afford the Celgene Defendants with such notice. As such, the MSP Plaintiffs' reliance on statements made during the August 29, 2022 status conference is unavailing.

The MSP Plaintiffs further contend that the Celgene Defendants were on notice that the MSP Plaintiffs' co-pay allegations were being asserted under Count I based on briefing and rulings made by Judge Hammer in connection with a motion to sever that had been filed by CDF and PAN. (MSP Supp. Opp. at 2–4). More specifically, on November 10, 2022, CDF and PAN moved to sever Counts II and III (Federal RICO Claims), Count VIII (Florida RICO Claim); and Counts VI (Unfair and Deceptive Trade Practices Claims Under State Law) and VII (Unjust Enrichment Claim) to the extent they concern co-pay assistance, from the remainder of the counts, including the antitrust counts that had been brought against the Celgene Defendants. (*MSP Recovery Series*

fact serve their motion to dismiss papers on the MSP Plaintiffs on August 26, 2022. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 108)).

LLC et al. v. Celgene Corporation et. al., Civil Action No. 21-20451 (D.E. Nos. 147 & 148)). The MSP Plaintiffs point out that in support of their motion to sever, the Charity Defendants contended that "[t]his action involves two distinct sets of claims—antitrust on one hand, and class action co-pay on the other." (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 147-1 at 1)). The MSP Plaintiffs state that in response to the motion, they maintained that the co-pay allegations "were critical to and an inextricably intertwined part of the successful execution of Celgene's antitrust schemes." (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 162 at 1)). On April 26, 2023, Judge Hammer denied the Charity Defendants' Motion to Sever. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 192 & 193)). The MSP Plaintiffs argue that Judge Hammer's opinion accurately describes their allegations by stating:

> Plaintiffs' antitrust and co-pay claims against all Defendants arise out of the same transaction, occurrence, or series of transactions or occurrences. The copay claims are, on the face of the Second Amended Complaint, part and parcel of the alleged anticompetitive scheme by the Celgene Defendants to reduce or prevent generics entering the marketplace, and raise the cost of the Drugs repeatedly to maximize profit.

MSP Recovery Claims, Series LLC v. Celgene Corp., No. 21-20451, 2023 WL 3092183, at *5 (D.N.J. Apr. 26, 2023). The MSP Plaintiffs contend that their briefing on the motion to sever and Judge Hammer's ruling indicate that the Celgene Defendants were on proper notice that their co-pay allegations were being brought under their antitrust counts, including Count I. (MSP Supp. Opp. at 3–4). The Court is not convinced. Again, as the Celgene Defendants point out (Celgene Supp. Reply at 6), the MSP Plaintiffs' briefing on the motion to sever, filed on November 21, 2022, and Judge Hammer's decision on the motion to sever, entered on April 26, 2023, were both entered *after* the Celgene Defendants had already served their motion to dismiss on the MSP

Plaintiffs on August 26, 2022 and their reply on November 14, 2022. (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 85 & 108)). As such, the MSP Plaintiffs' briefing on the motion to sever, filed on November 21, 2022, and Judge Hammer's decision on the motion to sever, entered on April 26, 2023, could not have provided the Celgene Defendants with notice before they briefed their motion to dismiss that the MSP Plaintiffs' co-pay allegations were being asserted under Count I.

Further, as the Celgene Defendants note, Judge Hammer's decision examined the standards for severance and joinder under Federal Rules of Civil Procedure 20 and 21. (Celgene Supp. Reply at 8). As part of that inquiry, Judge Hammer considered whether the antitrust allegations and co-pay allegations arose out of the "same transaction" and posed "common question[s]" as outlined in Rule 20(a)(1). *MSP Recovery Claims, Series LLC*, 2023 WL 3092183, at *5–6. In their briefing on the motion to sever, the MSP Plaintiffs contended that the antitrust allegations and co-pay allegations arose out of the same transaction and occurrence. On the one hand, the MSP Plaintiffs "maintain[ed] that the Celgene Defendants were able to exclude generics from the market via their antitrust schemes, such as refusing samples to generic competitors and initiating sham litigation." *Id.* at *4. According to the MSP Plaintiffs, "these alleged acts of exclusion enabled the Celgene Defendants to raise the prices of the Drugs repeatedly." *Id.* On the other hand, they contended that the co-pay scheme allowed Celgene to further raise the cost of its Drugs by eliminating price sensitivity from patients and doctors. *Id.* In other words, the MSP Plaintiffs argued that the co-pay allegations arose out of the same transaction and occurrence as the alleged antitrust scheme because "the co-pay scheme was another method for allowing Celgene to raise its prices to 'supra-competitive levels' without having to consider price sensitivity." *Id.* Judge Hammer agreed with the MSP Plaintiffs, stating that "[t]he common thread in [the MSP] Plaintiffs' claims is the Celgene

Defendants' desire" on the one hand "to keep generics out of the market via their antitrust scheme" and on the other hand "their concomitant use of the co-pay scheme to increase Drug prices without negatively impacting the Celgene Defendants' market reach." *Id.* at *5. However, the fact that Celgene's acts of exclusion and use of co-pay contributions both had the effect of increasing prices for Thalomid and Revlimid—thereby arising out of the "same transaction" and posing "common question[s]"—does not mean that the co-pay scheme was itself an act of exclusion within the antitrust scheme that blocked generic entry. Again, allegations that co-pay contributions increased prices say nothing about how those contributions delayed and blocked generic competition, which is the central component of the MSP Plaintiffs' Section 2 claim. Accordingly, because the MSP Plaintiffs' Second Amended Complaint (i) maintains a distinction between allegations of anticompetitive conduct on the one hand, through which Celgene allegedly kept generic competitors off the market (MSP SAC ¶¶ 40–501), and allegations of a co-pay circumvention scheme on the other hand, through which Celgene was able to artificially inflate its prices for Revlimid and Thalomid (*Id.* ¶¶ 502–52); (ii) wholly fails to mention the co-pay circumvention scheme in Count I, which alleges violations of Section 2 of the Sherman Act; and (iii) contains no allegations regarding how the co-pay circumvention scheme "delay[ed] and block[ed] entry of AB-rated generic equivalents of Thalomid and Revlimid," which is central to the MSP Plaintiffs' Section 2 claim, the Court finds that the MSP Plaintiffs' factual allegations did not put Celgene on sufficient notice that the co-pay allegations were being brought under Count I. As such, to the extent the MSP Plaintiffs purport to assert their co-pay allegations under Count I of the Second Amended Complaint, any such theory cannot proceed.[106]

[106] At oral argument, the MSP Plaintiffs suggested, based on "preliminary research," that Celgene's co-pay scheme amounted to an antitrust violation under a theory of predatory pricing that would "dissuade or discourage potential competitors from coming on the market." (Sept. 8, 2023 Oral Arg. at 229:8–16). That theory, however, is wholly absent from the face of the MSP Plaintiffs' Second Amended Complaint. And regardless, "[p]redatory pricing

vii. Sherman Act Claims Conclusion

Section 2 Claims. As noted above, the Insurer Plaintiffs and MSP Plaintiffs allege that the Celgene Defendants took a series of actions in furtherance of an overall scheme to violate Section 2 of the Sherman Act. (Opp. Br. at 13). More specifically, they argue that they plausibly allege that Celgene and later BMS delayed and stunted generic competition through a scheme that consisted of, *e.g.*, (i) citing the REMS safety programs as a pretext for refusing to sell generics samples; (ii) entering into an anticompetitive settlement agreement with Natco and reinforcing the anticompetitive effects of that agreement through later settlements with later would-be generics (iii) obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; and (iv) prosecuting over a dozen patent litigations where they had no realistic likelihood of prevailing on the merits. (*Id.* at 13–14). The MSP Plaintiffs also contend that the Celgene Defendants perpetuated this scheme by executing a co-payment circumvention scheme with CDF and PAN to fund patient copays of its Thalomid and Revlimid drugs, which caused both the number of prescriptions and the price of Thalomid and Revlimid to increase and, in turn, caused the MSP Plaintiffs' Assignors to overpay for those drugs. (MSP SAC ¶¶ 510–21). However, for the foregoing reasons, the Court finds that the alleged monopolistic scheme consists of (i) insufficiently pled acts; (ii) acts shielded from antitrust liability based on the *Noerr-Pennington* doctrine; (iii) acts for which the Insurer Plaintiffs and MSP Plaintiffs have not adequately pled antitrust injury, standing alone; and (iv) in the case of the MSP Plaintiffs, acts that failed to place the Celgene Defendants on sufficient notice of an antitrust violation under Section 2 of the

may be defined as pricing below an appropriate measure of cost for the purpose of eliminating competitors in the short run and reducing competition in the long run." *Cargill, Inc. v. Monfort of Colo.*, 479 U.S. 104, 117 (1986). Here, in contrast, the MSP Plaintiffs allege that the co-pay circumvention scheme allowed Celgene to artificially inflate its prices for Revlimid and Thalomid. (MSP SAC ¶¶ 502–52). As such, it is unclear how a theory of predatory pricing could even apply to the co-pay allegations.

Sherman Act. Whether taken separately or as an overall scheme, such acts as pled do not constitute impermissible activity under Section 2 of the Sherman Act. *See Eatoni*, 486 Fed. App'x. at 191 ("[When] alleged instances of misconduct are not independently anti-competitive . . . they are not cumulatively anticompetitive either." (citation omitted)); *Solodyn*, 2015 WL 5458570, at *13 (concluding that a complaint failed to state a Section 2 claim under an "overarching scheme" theory when none of the alleged conduct was independently anticompetitive); *Intergraph*, 195 F.3d at 1366–67 (Fed. Cir. 1999) (same); *Am. Nat'l Mfg. Inc.*, 2016 WL 9450472, at *9. As such, the Insurer Plaintiffs' and MSP Plaintiffs' claims under Section 2 of the Sherman Act are DISMISSED *without prejudice*. The Court will grant the Insurer Plaintiffs and MSP Plaintiffs one final opportunity to amend this claim. *See Prudential Ins. Co. of Am. v. Bank of Am., Nat'l Ass'n*, 14 F. Supp. 3d 591, 596 (D.N.J. 2014) (quoting *New York v. Hill*, 528 U.S. 110, 118 (2000)) (Dismissal of a complaint with prejudice is a "'harsh remedy'" that "is [only] appropriate if amendment would be inequitable or futile.").

Section 1 Claims. As recounted above, the Insurer Plaintiffs allege that the Celgene Defendants violated Section 1 of the Sherman Act by entering into an anticompetitive settlement agreement with Natco. (Humana Am. Compl. ¶¶ 570–81). The Court finds that, because any such claim cannot proceed under either a reverse payment or market allocation theory, their Section 1 claim is DISMISSED *without prejudice*. The Insurer Plaintiffs will have one final opportunity to amend this claim.

D. State Law Claims

i. The Insurer Plaintiffs' State Law Claims

a. Humana's, Cigna's, and Molina's State Law Claims

The Insurer Plaintiffs additionally raise claims pursuant to state law.[107] To support subject matter jurisdiction in this Court, Plaintiffs Humana and Cigna cite to 28 U.S.C. § 1331, 28 U.S.C. § 1337, and 28 U.S.C. § 1332. (Humana Am. Compl. ¶ 12; *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686 (D.E. No. 40 ¶ 12)). Molina cites to 28 U.S.C. § 1337 and 28 U.S.C. § 1332. *Molina Healthcare, Inc. v. Celgene Corporation, et al.*, Civil Action No. 22-4561 (D.E. No. 7 ¶ 12). Diversity jurisdiction exists under Section 1332 where the amount in controversy exceeds $75,000 and the citizenship of the parties is completely diverse. *Midlantic Nat'l Bank v. Hansen*, 48 F.3d 693, 696 (3d Cir. 1995) (citing *Carden v. Arkoma Assocs.*, 494 U.S. 185, 187 (1990)); 28 U.S.C. § 1332. And "[c]omplete diversity requires that, in cases with multiple plaintiffs or multiple defendants, no plaintiff be a citizen of the same state as any defendant." *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 419 (3d Cir. 2010) (citations omitted). A corporation is a citizen of the state where it has its principal place of business as well as the state of its incorporation. 28 U.S.C. § 1332(c)(1). Here, neither Humana, nor Cigna, nor Molina has satisfied the requirement of complete diversity. (Humana Am. Compl. ¶¶ 16 & 21–22 (alleging that Plaintiff Humana is incorporated in Delaware and Defendants Celgene and BMS are also incorporated in Delaware); *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686 (D.E. No. 40 ¶¶ 16 & 21–22 (alleging that Plaintiff Cigna is a corporation organized under the laws of Delaware and Defendants Celgene and BMS are also incorporated in Delaware);

[107] As discussed previously, on October 17, 2022, the actions initiated separately by Humana, Cigna, Molina, Blue Cross, and Health Care were consolidated under lead docket Civil Action 19-7532. (D.E. No. 95). While "consolidation is permitted as a matter of convenience and economy in administration," it "does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." *Cella v. Togum Constructeur Ensembleier en Industrie Alimentaire*, 173 F.3d 909, 912 (3d Cir. 1999) (quoting *Johnson v. Manhattan Ry. Co.*, 289 U.S. 479, 496–97 (1933)). As such, "while a consolidation order may result in a single unit of litigation, such an order does not create a single case for jurisdiction purposes." *Id.* Accordingly, the Court considers each suit initiated by the Insurer Plaintiffs separately, to determine whether it has jurisdiction over the Insurer Plaintiffs' state law claims. *Deluxe Bldg. Sys., Inc. v. Constructamax, Inc.*, 94 F. Supp. 3d 601, 608 (D.N.J. 2013) ("I must notionally deconsolidate these cases for the purpose of analyzing diversity. I will therefore analyze subject matter jurisdiction separately as to the Deluxe Action and the Whitlock Action, despite their consolidation.").

Molina Healthcare, Inc. v. Celgene Corporation, et al., Civil Action No. 22-4561 (D.E. No. 7 ¶¶ 15 & 20–21) (alleging that Plaintiff Molina is incorporated in Delaware and Defendants Celgene and BMS are also incorporated in Delaware). Jurisdiction under 28 U.S.C. § 1332 is thus improper based on the face of Humana's, Cigna's, and Molina's Operative Complaints.

While absent diversity a court does not have subject matter jurisdiction over state law claims, a court may exercise supplemental jurisdiction over state law claims packaged with federal claims. 28 U.S.C. § 1367.[108] Nevertheless, federal law permits a district court, within its discretion, to decline to exercise supplemental jurisdiction over a claim if "the district court has dismissed all claims over which it has original jurisdiction." 28 U.S.C. 1367(c)(3). "[T]he power of the [C]ourt to exercise pendent jurisdiction, though largely unrestricted, requires, at a minimum, a federal claim of sufficient substance to confer subject matter jurisdiction on the [C]ourt." *City of Pittsburgh Comm'n on Hum. Rels. v. Key Bank USA*, 163 Fed. App'x. 163, 166 (3d Cir. 2006) (quoting *Tully v. Mott Supermarkets, Inc.*, 540 F.2d 187, 195 (3d Cir. 1976)). "[I]f it appears that all federal claims are subject to dismissal, the [C]ourt should not exercise jurisdiction over remaining claims unless '*extraordinary* circumstances' exist." *Id.* (quoting *Tully*, 540 F.2d at 195) (emphasis added). As such, because the Court has dismissed the federal claims in Humana's, Cigna's, and Molina's Operative Complaints upon which its original subject-matter jurisdiction is predicated, the Court declines to exercise supplemental jurisdiction over their state law claims.[109] *See Cable Line, Inc. v. Comcast Cable Commc'ns of Pa., Inc.*, No. 16-1000, 2018 WL 2209518,

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[108] In fact, Humana and Cigna provide that this Court has supplemental jurisdiction over their state law claims pursuant to 28 U.S.C. § 1367. (Humana Am. Compl. ¶ 13; *Cigna Corporation v. Celgene Corporation, et al.*, Civil Action No. 21-11686 (D.E. No. 40 ¶ 13)).

[109] While Humana, Cigna, and Molina also cite to 28 U.S.C. § 1337, that statute does not give the Court any basis to exercise jurisdiction over their state law claims. 28 U.S.C. § 1337 (Providing that district courts have original jurisdiction over "any civil action or proceeding arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies."); *R.R. Const. Co. of S. Jersey v. A.P. Const., Inc.*, No. 10-6190, 2011 WL 2975204, at *5–6 (D.N.J. July 21, 2011).

at *11 (M.D. Pa. May 14, 2018), *aff'd*, 767 F. App'x 348 (3d Cir. 2019). Accordingly, Counts III through VII of Humana's and Cigna's Operative Complaints are DISMISSED *without prejudice*. Likewise Counts I through V of Molina's Operative Complaint are DISMISSED *without prejudice*.

b. Blue Cross's and Health Care's State Law Claims

To support subject matter jurisdiction in this Court, Plaintiffs Blue Cross and Health Care also allege jurisdiction pursuant to 28 U.S.C. § 1332. (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶ 12); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶ 12)). As stated, diversity jurisdiction exists under Section 1332 where the amount in controversy exceeds $75,000 and the citizenship of the parties is completely diverse. *Midlantic Nat'l Bank*, 48 F.3d at 696; 28 U.S.C. § 1332. Unlike Humana, Cigna, and Molina, Blue Cross, and Health Care appear to have satisfied both the amount in controversy and complete diversity requirements. (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 at 4–8, 127–32, 160–65 & 175–76); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 at 3–7, 123–28, 156, 178 & 191–92)). As such, the Court can exercise jurisdiction over these state law claims pursuant to 28 U.S.C. § 1332.

Counts II and III. Counts II and III of Blue Cross's and Health Care's Operative Complaints raise allegations against the Celgene Defendants for Monopolization and Monopolistic Scheme under various state statutes and Attempted Monopolization under various state statutes, respectively. (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 575–85); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 648–58)). In support of Counts II and III, Blue

Cross and Health Care allege that the Celgene Defendants delayed and stunted generic competition through a scheme that consisted of, *e.g.*, (i) citing the REMS safety programs as a pretext for refusing to sell generics samples; (ii) paying off the first-to-file, would-be generic competitor through a secret, "pay-for-delay" settlement agreement; and reinforcing the first-to-file payoff through later settlements with later would-be generics; (iii) obtaining (sometimes by fraud) and listing unenforceable and invalid patents in the Orange Book; and (iv) prosecuting over a dozen patent litigations where they had no realistic likelihood of prevailing on the merits. (Opp. Br. at 13–14). The Celgene Defendants move to dismiss these counts and argue that those Counts cannot proceed as pled for the same reasons that the Section 2 Sherman Act claim cannot proceed. For the reasons set forth below, the Court agrees with the Celgene Defendants.

As the Celgene Defendants point out, the state monopolization statutes asserted under Counts II and III either (i) contain explicit harmonization provisions, which explain that those statutes should be interpreted in accordance with federal antitrust law, or (ii) have been interpreted, according to courts within that state, in accordance with federal antitrust law. (Appendix C to Mov. Br. (explaining that all statutes asserted in Counts II and III should be interpreted in accordance with federal antitrust law either under harmonization provision or state law interpreting those statutes)). Further, at oral argument the Insurer Plaintiffs agreed that the state statutes asserted in Counts II and III should be interpreted in accordance with federal antitrust law. (Tr. of Aug. 18, 2023 Oral Arg. at 104:8–12).[110] As such, for the same reasons the Court set forth above

[110] In their moving brief, the Celgene Defendants argue that the state monopolization statutes asserted in Counts II and III should be interpreted in accordance with federal law and, more specifically, according to the law of the Circuit of those respective states. (Mov. Br. at 46). At oral argument, the Insurer Plaintiffs contended that these statutes should merely be interpreted in accordance with federal law—that is, in accordance with precedent from the Supreme Court and Third Circuit specifically. (Tr. of Aug. 18, 2023 Oral Arg. at 105:10–16). The Court need not resolve this dispute because, even under the Insurer Plaintiffs' suggested approach, the Court finds that the claims under Counts II and III of Blue Cross's and Health Care's Operative Complaints cannot proceed. More specifically, as recounted above, the Court finds that the Insurer Plaintiffs have failed to plead an adequate claim under Section 2 of the Sherman Act after analyzing binding precedent from the Supreme Court and Third Circuit and after considering

in Section III(C) in finding that the Insurer Plaintiffs' allegations cannot support a claim under Section 2 of the Sherman Act, the Court likewise finds that those same allegations cannot support claims under the state statutes that are asserted under Counts II and III of Blue Cross's and Health Care's Operative Complaints. Accordingly, Blue Cross's and Health Care's claims under Counts II and III are DISMISSED *without prejudice*.

Count I. Count I of Blue Cross's and Health Care's Operative Complaints raises allegations against the Celgene Defendants for Conspiracy and Combination in Restraint of Trade under various state statutes. In support of Count I, Blue Cross and Health Care allege that the Celgene Defendants entered into an unlawful settlement agreement with Natco that restrained, and continues to restrain, competition in the market for Revlimid and/or its generic equivalents. (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 563–74); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 636–47)). The Celgene Defendants move to dismiss Count I and argue that this Count cannot proceed as pled for the same reason that the Celgene-Natco settlement cannot proceed as pled under federal law. (Tr. of Aug. 18, 2023 Oral Arg. at 272:9–22). For the reasons set forth below, the Court agrees with the Celgene Defendants.

The state statutes asserted under Count I either (i) contain explicit harmonization provisions, which explain that those statutes should be interpreted in accordance with federal antitrust law, or (ii) have been interpreted, according to courts within that state, in accordance with federal antitrust law. (Appendix C to Mov. Br.); *see also* K.S.A.2013 Supp. 50–163(b) ("Except as otherwise provided in subsections (d) and (e), the Kansas restraint of trade act shall be construed

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case law from other Circuits as persuasive authority. As such, for the same reasons the Court set forth above in Section III(C) in finding that the Insurer Plaintiffs' allegations cannot support a claim under Section 2 of the Sherman Act, the Court likewise finds that those same allegations cannot support claims under Counts II and III of Blue Cross's and Health Care's Operative Complaints.

in harmony with ruling judicial interpretations of federal antitrust law by the United States supreme court."); *Rockholt Furniture, Inc. v. Kincaid Furniture Co.*, No. 96-0588, 1998 WL 1661384, at *8 (E.D. Tenn. July 6, 1998), *aff'd sub nom. Rockholt Furniture, Inc. v. Kincaid Furniture Co.*, 188 F.3d 509 (6th Cir. 1999) ("The State [of Tennessee] anti-trust statute passed in 1891 is quite similar to the Sherman Anti-Trust Act passed by Congress in 1890 . . . In Section III(A) of this Memorandum, the Court concluded Rockholt has not presented sufficient evidence to support its claim of a Sherman Act violation. For the same reasons, the Court concludes Rockholt's evidence fails with respect to any claim under the state antitrust law." (alteration in original) (citations omitted)). Further, at oral argument the Insurer Plaintiffs agreed that the state statutes asserted in Count I should be interpreted in accordance with federal antitrust law. (Tr. of Aug. 18, 2023 Oral Arg. at 273:4–11 (explaining that only the unjust enrichment and consumer protection claims should not be interpreted in accordance with federal law)). As such, for the same reasons the Court set forth above in Section III(C)(iii) in finding that the Insurer Plaintiffs' allegations related to the Celgene-Natco agreement cannot support a claim under the Sherman Act, the Court likewise finds that those same allegations cannot support claims under the state statutes asserted in Count I of Blue Cross's and Health Care's Operative Complaints. Accordingly, Blue Cross's and Health Care's claims under Count I are DISMISSED *without prejudice*.

Count IV. Count IV of Blue Cross's and Health Care's Operative Complaints raises allegations against the Celgene Defendants for Unfair and Deceptive Trade Practices under various state statutes. The Celgene Defendants move to dismiss Count IV, arguing that "where the same conduct allegedly supports both antitrust and unfair competition claims, a ruling that no antitrust claim is stated precludes a tag-on claim for unfair competition." (Mov. Br. at 48 n.19 (citing *In re Plavix Indirect Purchaser Antitrust Litig.*, No. 06-0226, 2011 WL 335034, at *4-5 (S.D. Ohio Jan.

31, 2011)). Further, the Celgene Defendants argue that Count IV should be dismissed because Blue Cross and Health Care plead a single collective count for consumer fraud in violation of multiple state statutes, without setting forth the elements or explaining how the listed statutes apply to the facts of the case, despite the fact that the statutes listed in Count IV require significantly different showings. (Mov. Br. at 48 n.19 & 54–55). For the reasons set forth below, the Court finds that Count IV must be DISMISSED.

To start, the Celgene Defendants move to dismiss Count IV, arguing that "where the same conduct allegedly supports both antitrust and unfair competition claims, a ruling that no antitrust claim is stated precludes a tag-on claim for unfair competition." (Mov. Br. at 48 n.19 (citing *In re Plavix*, 2011 WL 335034, at *4–5)). To the extent the state laws asserted under Count IV are commensurate with federal antitrust law and the Insurer Plaintiffs' allegations are insufficient to state a federal cause of action under the Sherman Act, Count IV must also be dismissed. In fact, courts have dismissed state consumer protection and unfair trade practices claims that simply mirror deficient federal antitrust claims. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003), *aff'd*, 466 F.3d 187 (2d Cir. 2006) (dismissing twenty-one state law consumer protection and unfair competition claims where the claims track the allegations underlying the deficient federal antitrust claims); *see also In re Aluminum Warehousing Antitrust Litig.*, No.13-2481, 2014 WL 4743425, at *1–2 (S.D.N.Y. Sept. 15, 2014).

Blue Cross and Health Care argue that the state consumer protection laws under Count IV are distinct from their antitrust counts and as such cannot be automatically dismissed in the event the federal antitrust claims cannot proceed. (Tr. of Aug. 18, 2023 Oral Arg. at 273:7–11). Nevertheless, even if the state consumer protection laws under Count IV are not co-extensive with the antitrust counts, the Court finds that Count IV must still be dismissed because it fails to properly

plead each state law. The Court finds that the court's decision in *McCalley v. Samsung Elecs. Am., Inc.*, No. 07-2141, 2008 WL 878402 (D.N.J. Mar. 31, 2008) is instructive on this point. In *McCalley*, the "[p]laintiff allege[d] violations of the unfair and deceptive acts and practices statutes of forty-four states and the District of Columbia." *McCalley*, 2008 WL 878402, at *9. The court found that the dismissal of these claims was warranted because the plaintiff "fail[ed] to allege even the elements of the various statutes, or facts permitting th[e] [c]ourt to draw inferences that the elements exist." *Id*. (citing *Kost v. Kozakewicz*, 1 F.3d 176, 183 (3d Cir. 1993)). Because the plaintiff offered little more than "labels and conclusions" in asserting that the unfair and deceptive acts and practices statutes of forty-four states had been violated, the court dismissed the claim. *Id.* (internal quotation marks omitted) (quoting *Twombly*, 550 U.S. at 555). The court in *McGarvey v. Penske Auto. Grp., Inc.*, 639 F. Supp. 2d 450 (D.N.J. 2009), *opinion vacated in part on reconsideration*, No. 08-5610, 2010 WL 1379967 (D.N.J. Mar. 29, 2010) reached a similar conclusion, dismissing the plaintiffs' collective consumer fraud act claim because the "[p]laintiffs d[id] not even set forth the elements of the fifteen causes of action they assert[ed]" in their collective consumer fraud claim "or explain how [those statutes] appl[ied] to the facts of th[e] case." *McGarvey*, 639 F. Supp. 2d at 465–66; *see also In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13- 2445, 2017 WL 4642285, at *13 (E.D. Pa. Oct. 17, 2017) (dismissing state consumer protection statute claims where complaint did not contain specific reference to the various state standards under which the claims were made or tailor facts to suit the significant differences among the states' consumer protection laws).

The Court finds that the same conclusion is warranted here. More specifically, in Count IV, Blue Cross and Health Care allege that the Celgene Defendants violated the unfair and deceptive trade practices statutes of 35 states and the District of Columbia. (*Blue Cross and Blue*

Shield Association v. Celgene Corporation, et al., Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 586–89); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 659–62). In bringing this Count, Blue Cross and Health Care merely "incorporate by reference" all of the preceding allegations and then add the conclusory statement that "Celgene engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below." (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 586–89); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 659–62). Blue Cross's and Health Care's Operative Complaints do "not contain specific reference to the various state standards under which the claims are made or tailor facts to suit the significant differences among States' consumer protection laws." *Avenarius v. Eaton Corp.*, 898 F. Supp. 2d 729, 739 (D. Del. 2012) (internal quotation marks and citation omitted). As recounted above, multiple courts, including within this Circuit, have held that "merely listing statutes that could provide possible causes of action without explaining even the broadest contours of how those statutes were violated 'is insufficient to state a claim.'" *Aluminum Warehousing*, 2014 WL 4743425, at *1 (quoting *In re Trilegiant Corp.*, No. 12-0396, 2014 WL 1315244, at *35 (D. Conn. Mar. 28, 2014)) (further citations omitted); *see also McGarvey*, 639 F. Supp. 2d at 465–66 (granting motion to dismiss collective state consumer fraud acts claim because "[p]laintiffs do not even set forth the elements of the fifteen causes of action they assert . . . or explain how the fifteen listed statutes apply to the facts of this case"); *see also Suboxone*, 2017 WL 4642285, at *13 (dismissing state consumer protection statute claims where the complaint "d[id] not contain specific reference to the various state standards under which the claims were made or tailor facts

to suit the '*significant* differences among States' consumer protection laws"). As the Supreme Court explained in *Twombly*,

> While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitlement to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Twombly, 550 U.S. at 555 (internal citations omitted).[111] Here, Blue Cross and Health Care fail to allege even the elements of the various statutes or facts permitting this Court to draw inferences that the elements have been met. As such, Count IV of Blue Cross's and Health Care's Operative Complaints must be DISMISSED. Nevertheless, it is DISMISSED *without prejudice*. *See Humira*, 465 F. Supp. 3d at 848 ("[T]he problem here is that read as a whole, the complaint sounds in antitrust, and once it is understood to not state such a claim, something more (perhaps not much) must be offered other than statutory language or quotations from state caselaw to understand why the nonactionable antitrust conduct happens to limn the grievance of state prohibitions against unfairness or unconscionability.").

Count V. Count V of Blue Cross's and Health Care's Operative Complaints raises allegations against the Celgene Defendants for unjust enrichment in all states except Ohio and

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[111] The Court acknowledges that other courts have taken a contrary view. *See, e.g.*, *In re Seroquel XR Antitrust Litig.*, No. 20-1076, 2022 WL 2438934, at *21 (D. Del. July 5, 2022) ("Defendants' suggestion that the End-Payors must list the elements of every asserted state consumer protection statute and connect the pleaded facts to those elements goes too far." (citations omitted)); *see also Silva v. Hornell Brewing Co.*, No. 20-0756, 2020 WL 4586394, at *4 (E.D.N.Y. Aug. 10, 2020) (noting that the "[p]laintiff is required to plead the facts, not the details of the law."). Nevertheless, the Court is persuaded by the reasoning employed by courts within this district that have dismissed consumer fraud act claims where the plaintiffs did not set forth the elements of the causes of action they assert or explain how the statutes asserted apply to the facts of the case. *McGarvey*, 639 F. Supp. 2d at 465–66; *see also McCalley*, 2008 WL 878402, at *9. As those courts explained, a plaintiff is "required to 'set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist.'" *McGarvey*, 639 F. Supp. 2d at 465–66 (quoting *Kost*, 1 F.3d at 183); *see also McCalley*, 2008 WL 878402, at *9. Merely listing statutes that could provide possible causes of action without explaining even the broadest contours of how those statutes were violated is not sufficient to permit this Court to draw inferences that the elements of those various statutes exist. *McGarvey*, 639 F. Supp. 2d at 466.

Indiana. The Operative Complaints allege that Blue Cross and Health Care have conferred an economic benefit upon the Celgene Defendants in the form of profits from overcharges on Revlimid. (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 590–601); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 663–74)). The Celgene Defendants move to dismiss Count V, arguing that courts rightly hold that unjust enrichment may not supply a valid cause of action in states where plaintiffs have not made out viable antitrust or consumer protection claims. (Mov. Br. at 48 n.19 (citing *In re Packaged Seafood Prods. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1088 (S.D. Cal. 2017)). As such, the Celgene Defendants contend that insofar as Count V is premised on the same allegations that support the antitrust claims under the Sherman Act, Count V rises and falls with the success of those claims. For the reasons set forth below, the Court finds that Count V must be DISMISSED.

To start, in Count V, Blue Cross and Health Care allege that "[i]t would be inequitable under the unjust enrichment principles of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Revlimid." (*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 590–601); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 663–74)). However, the sole reason Blue Cross and Health Care allege that it would be inequitable for the Celgene Defendants to retain the alleged profits at issue is that they were obtained through the acts that form the basis of their antitrust claims, which this Court has concluded are not adequately pled. Indeed, Blue Cross's and Health Care's unjust enrichment claim incorporates by reference and is premised on the allegations regarding the acts that form the basis of their antitrust claims.

(*Id.*). As such, Blue Cross's and Health Care's unjust enrichment claims must be DISMISSED. *See, e.g., In re Treasury Sec. Auction Antitrust Litig.*, No. 15-2673, 2021 WL 1226670, at *16–17 (S.D.N.Y. Mar. 31, 2021) (dismissing unjust enrichment claim where the plaintiffs "failed to plead the antitrust violations that are the sole basis" for their unjust enrichment claim (internal quotation marks and citation omitted)); *In re Aluminum Warehousing Antitrust Litig.*, 2014 WL 4743425, at *4 (plaintiffs' "unjust enrichment claim . . . is predicated on defendants' alleged violations of antitrust or consumer protection laws, which the [c]ourt has dismissed . . . . Accordingly, [the unjust enrichment] claim warrants dismissal . . . ." (citations omitted)); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 542 (E.D. Pa. 2010); *Packaged Seafood*, 242 F. Supp. 3d at 1088.

Blue Cross and Health Care argue that their unjust enrichment claims under Count V are distinct from their antitrust counts and as such cannot be automatically dismissed in the event the federal antitrust claims cannot proceed. (Tr. of Aug. 18, 2023 Oral Arg. at 273:7–11). Nevertheless, even if the unjust enrichment claims under Count V are distinct from the antitrust counts, the Court finds that Count V of Blue Cross's and Health Care's Operative Complaints must still be dismissed because Blue Cross and Health Care have failed to adequately plead claims under every state law. The Court finds the court's decision in *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143 (E.D. Pa. 2009) instructive on this point. In *Wellbutrin XL*, the plaintiffs brought a claim against the defendants for unjust enrichment. *Wellbutrin XL*, 260 F.R.D. at 148, 167. The court found that the dismissal of this claim was warranted because the plaintiffs failed to link their claim to the law of any particular state. *Wellbutrin XL*, 260 F.R.D. at 167. In so holding, the court rejected the plaintiffs' argument "that the elements of unjust enrichment claims are substantially identical across all fifty states." *Id.* While noting that such an assertion is unlikely to be true, the court also stated that "cobbling together the elements of a claim of unjust enrichment from the

laws of the fifty states is no different from applying federal common law." *Id.* It further explained that "[u]njust enrichment is not a catch-all claim existing within the narrow scope of federal common law." *Id.* (citation omitted). As such, the court dismissed the plaintiff's claim of unjust enrichment.

Likewise, in *Miami Prod. & Chem. Co. v. Olin Corp.*, 546 F. Supp. 3d 223 (W.D.N.Y. 2021), the court found that the plaintiffs' conclusory allegations of unjust enrichment under the laws of all states except Ohio and Indiana did not comply with the relevant pleading standards. In dismissing these claims, the court noted that the plaintiffs merely "pleaded federal antitrust claims and the factual foundation for them," and then "allege[d] that those claims are also actionable as . . . unjust enrichment." *Miami Prod.*, 546 F. Supp. at 247 (quoting *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255 (D. Conn. 2015) (internal quotation marks omitted)). It stated that such a generic pleading does not satisfy Rule 8. *Id.* It emphasized that the plaintiffs "cannot simply enumerate a long list of state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law." *Id.* (quoting *Aggrenox*, 94 F. Supp. 3d at 255–56) (internal quotation marks omitted); *see also In re Opana ER Antritrust Litig.*, 162 F. Supp. 3d 704, 726 (N.D. Ill. 2016) (dismissing unjust enrichment claim where plaintiffs failed to account for any consequential differences that may exist among the state-law unjust enrichment claims).

The Court finds that the same conclusion is warranted here. More specifically, in Count V, Blue Cross and Health Care simply "incorporate by reference" all of the preceding allegations and then add the conclusory statement that it would be inequitable under the unjust enrichment principles of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Revlimid.

(*Blue Cross and Blue Shield Association v. Celgene Corporation, et al.*, Civil Action No. 21-10187 (D.E. No. 53 ¶¶ 590–601); *Health Care Service Corp., et al. v. Celgene Corporation, et al.*, Civil Action No. 21-6668 (D.E. No. 93 ¶¶ 663–74). While Blue Cross and Health Care bring claims for unjust enrichment under numerous state laws, they have not truly pleaded claims under those laws sufficient to show their entitlement to recovery under them as required by Federal Rule of Civil Procedure 8. *See Iqbal*, 556 U.S. at 678 ("A pleading that offers labels and conclusions or formulaic recitation of the elements of a cause of action will not do."). "Rather, they have pleaded antitrust claims and the factual foundation for them, and have merely alleged that those claims are also actionable . . . as unjust enrichment." *Opana*, 162 F. Supp. 3d at 726. Blue Cross's and Health Care's pleading on their unjust enrichment claims fails to account for any consequential differences that may exist among the undifferentiated state-law claims. *See Wellbutrin XL*, 260 F.R.D. at 167; *see also Miami Prod.*, 546 F. Supp. at 247–48 ("[T]he undifferentiated unjust enrichment claims set forth in the indirect purchaser complaint provide neither Defendants nor the Court with sufficient information to assess their adequacy." (citation omitted)). As such, the Court finds that Count V of Blue Cross's and Health Care's Operative Complaints must be DISMISSED. Nevertheless, it is DISMISSED *without prejudice*. *See Humira*, 465 F. Supp. 3d at 848 ("[T]he problem here is that read as a whole, the complaint sounds in antitrust, and once it is understood to not state such a claim, something more (perhaps not much) must be offered other than statutory language or quotations from state caselaw to understand why the nonactionable antitrust conduct happens to limn the grievance of state prohibitions against unfairness or unconscionability.").

ii. The MSP Plaintiffs' State Law Claims

The MSP Plaintiffs also raise state law claims in their Second Amended Complaint. However, to support subject matter jurisdiction in this Court, the MSP Plaintiffs cite only to 28

U.S.C. §§ 1331 and 1337. (MSP SAC ¶ 16). And they provide that this Court has supplemental jurisdiction over their state law claims pursuant to 28 U.S.C. § 1367. (*Id.* ¶ 18). Because the Court has dismissed the MSP Plaintiffs' federal claims upon which its subject-matter jurisdiction is predicated, and because the MSP Plaintiffs do not allege that there is subject matter jurisdiction under 28 U.S.C. § 1332 (*see* MSP SAC ¶ 16), the Court need not address the sufficiency of the MSP Plaintiffs' state law claims (Counts IV–VIII), and the Court declines to exercise supplemental jurisdiction over those state law claims. As such, Counts IV through VIII of the MSP Plaintiffs' Second Amended Complaint are dismissed *without prejudice*.[112]

IV. CONCLUSION

Based on the foregoing, the Celgene Defendants' motions (*In re Revlimid & Thalomid Purchaser Antitrust Litigation*, Civil Action No. 19-7532 (D.E. No. 104); *MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. No. 151)) and Charity Defendants' motions (*MSP Recovery Series LLC et al. v. Celgene Corporation et. al.*, Civil Action No. 21-20451 (D.E. Nos. 149 & 150)) are **GRANTED** and the Insurer Plaintiffs' and MSP Plaintiffs' Operative Complaints are dismissed in their entirety.[113] An appropriate Order follows.

Dated: June 6, 2024

s/ Esther Salas
Esther Salas, U.S.D.J.

[112] Because the Court declines to exercise supplemental jurisdiction over the MSP Plaintiffs' state law claims it does not reach the Celgene Defendants' and Charity Defendants' specific arguments in favor of dismissing these claims. (*See, e.g.*, Mov. Br. at 48 n.19 & 54–55, PAN Mov. Br. at 36–40; CDF Mov. Br. at 32–37).

[113] Because the Court dismisses the Insurer Plaintiffs' and MSP Plaintiffs' Operative Complaints in their entirety, the Court need not address the Celgene Defendants' arguments that the Insurer Plaintiffs and MSP Plaintiffs have failed to adequately allege claims against Celgene's parent company, BMS. (Mov. Br. at 57–59; Reply at 30).